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[71]申请人 陆渭明
地址 750004 宁夏回族自治区银川市宁夏医学院
[72]发明人 陆渭明

[74]专利代理机构 北京三友知识产权代理有限公司
代理人 马娅佳

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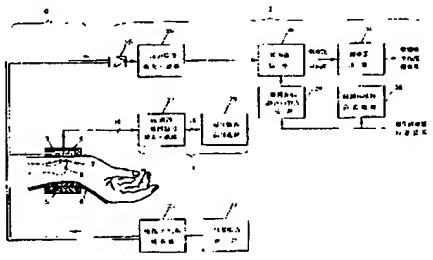
[54]发明名称 无创伤测量血压的方法和装置

[57]摘要

一种无创伤连续测量血压的方法和装置，将手根部相对于手腕部的夹角和手腕 部相对于前臂的转角分别固定在最适合测量桡动脉血压的角度上，至少采用一个加压 囊体和一个动脉脉搏传感器阵列压置于手腕部桡动脉处的皮肤表面上对桡动脉加压同 时检测桡动脉脉搏信号。它能利用容积振动法和容积补偿法原理很简单地、并且排除 体动等影响地在手腕部正确测量间断的和连续的桡动脉或/和尺动脉血压，同时还能消 除长时间连续测量对手部的血流循环和神经机能的影响。



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权 利 要 求 书

1、一种无创伤测量血压的测量定位方法，至少采用一动脉脉搏传感器压置于手腕部桡动脉处的皮肤表面上检测桡动脉脉搏信号，其特征在于至少将手根部相对于手腕部的夹角固定在最适合测量桡动脉血压的角度上；该角度能降低肌腱的位置和使桡动脉接近于桡骨。

2、根据权利要求 1 所述的无创伤测量血压的测量定位方法，其特征在于测量桡动脉血压时，所述的手根部的背侧面与手腕部的背侧面最好形成 100～175° 的夹角；

3、根据权利要求 1 所述的无创伤测量血压的测量定位方法，其特征在于测量桡动脉血压时，将手腕部相对于前臂的转角固定在最适合测量桡动脉血压的角度上；该角度能使桡动脉进一步接近于桡骨。

4、根据权利要求 3 所述的无创伤测量血压的测量定位方法，其特征在于测量桡动脉血压时，所述的手腕部相对于前臂的转角为手腕部的掌侧面相对于前臂靠近肘关节部分的掌侧面形成的向内的转角最好为 30～100° 。

5. 一种采用如权利要求 1 所述的的测量定位方法的无创伤测量血压的方法，包括有如下步骤：

A、至少在手腕部桡骨末端朝向掌侧的最高凸起点处的皮肤表面上设置一个动脉脉搏传感器阵列和一个加压囊体，并保持动脉脉搏传感器阵列以及加压囊体相对于该点的位置不变；

B、此时控制加压囊体压力在下限低于被测者可能的平均压、上限高于被测者可能的收缩压的范围内进行变化；

C、在囊体压力变化的同时，由脉搏传感器阵列从手腕部多个位置上测量出整个压力变化过程中的桡动脉搏信号，并送到最佳脉搏信号选择电路；由于离桡动脉近的传感器测得的脉搏信号振幅大，而压力传递好的位置测得的脉搏信号平均压和收缩压低，为了在桡动脉上方找到压力传递最好的点，从阵列里平行于桡动脉排列的所有列传感器测得的所有列脉搏信号中振幅最大点时的振幅与其它列相比为最大的一列脉搏信号中，选出一路在囊体加压过程中具有振幅最大点、以及在囊体压力高于振幅最大点所对应的压力后具有振幅开始基本上消失并且振幅开始基本不变的点，并且其振幅最大点以及基本消失点所对应的囊体压力与其它路的相比为最低的脉搏信号作为最佳脉搏信号；

D、将选出的最佳脉搏信号用于无创伤地测量桡动脉血压。

6、根据权利要求 5 所述的一种无创伤测量血压的方法，其特征在于动脉脉搏传感器阵列最好位于加压囊体的加压面积中心，使得当测得最佳脉搏信号的传感器位于传感器阵列中心时，压力传递深度最大的加压囊体的面积中心正好能对准这个传感器所对应的压力传

递最好的位置。

7、根据权利要求 6 所述的一种无创伤测量血压的方法，其特征在于选出最佳脉搏信号后，用最直观的方式显示出测得最佳脉搏信号的传感器位于传感器阵列的哪个位置上；在固定囊体时，根据这个显示来调节囊体的固定位置，使得最佳传感器位置正好位于阵列的中心；

8、根据权利要求 7 所述的一种无创伤测量血压的方法，其特征在于在进行长时间血压测量时，可自动地检查最佳传感器位置是否位于阵列的中心，当偏离中心过大时，发出须重新调整加压囊体固定位置的警告信号。

9、 根据权利要求 5 所述的一种无创伤测量血压的方法，其特征在于最好将动脉脉搏传感器阵列固定在囊体的朝向手腕的壁的内侧面， 使其不影响囊体内侧壁均匀地压迫手腕表面。

10、根据权利要求 5 所述的一种无创伤测量血压的方法，其特征在于测量桡动脉血压时，最好还应将手根部略向小拇指侧转动，使手根部的中心线相对于手腕部掌侧面的中心线形成 10～40° 的转角，大拇指下方的手根凸起部不妨碍囊体的固定绑带贴紧手腕。

11、根据权利要求 5 所述的一种无创伤测量血压的方法，其特征在于消除手根部与手腕部相接的部分与靠近前臂部分的直径差，同时将这部分的由于手根部向背侧弯曲而内陷的复杂形状添补成一个规则的圆柱面，防止囊体加压时发生的囊体整体沿手腕长轴方向向手根部移动，便于囊体的稳固。

12、根据权利要求 5 所述的一种无创伤测量血压的方法，其特征在于使囊体的固定装置以及手腕的固定装置与手腕部有尽可能大的接触面积，尽可能减小囊体加压时囊体固定装置对手腕部其它部分的压力。

13、根据权利要求 5 所述的一种无创伤测量血压的方法，其特征在于将选出的最佳脉搏信号用于容积振动法无创伤测量平均压和收缩压。

14、根据权利要求 5 所述的一种无创伤测量血压的方法，其特征在于将选出的最佳脉搏信号用于容积补偿法无创伤连续测量桡动脉血压波形。

15、根据权利要求 5 所述的一种无创伤测量血压的方法，其特征在于将选出的最佳脉搏信号交替地用于容积振动法无创伤测量平均压、收缩压和用于容积补偿法无创伤连续测量桡动脉血压波形。

16、根据权利要求 5 所述的一种无创伤测量血压的方法，其特征在于可同时在桡动脉和尺动脉上分别各设置一个脉搏传感器和加压囊体，在两根动脉上交替地进行血压测量。

17、根据权利要求 16 所述的一种无创伤测量血压的方法，其特征在于尺动脉脉搏传感器也可为相互并联的光电传感器，最好在尺动脉加压囊体的加压范围内沿垂直于尺动脉的方向上排列 2 个以上相互并联的光电传感器。

18、根据权利要求 16 所述的一种无创伤测量血压的方法，其特征在于对尺动脉进行血压测量时，可以利用桡动脉血压测量结果作为标准对尺动脉血压测量结果进行校准。

19、根据权利要求 16 所述的一种无创伤测量血压的方法，其特征在于利用桡动脉血压测量结果对尺动脉血压测量结果进行校准时，求出测得的桡动脉的平均压与测得的尺动脉脉搏振幅最大点所对应的囊体压力的差 Di，同时求出测量尺动脉压的过程中，囊体压力等于桡动脉的收缩压时的尺动脉脉搏振幅与其最大振幅的比例 Pi。这样，在后面再测量尺动脉血压时，每次将新测得的尺动脉脉搏振幅最大点所对应的囊体压力减去 Di，得出这次的平均压；同时，在体囊压力低于这次的平均压的范围内找到尺动脉脉搏振幅中与其最大振幅成比例 Pi 的点所对应的囊体压力，得出这次的收缩压。

20、根据权利要求 19 所述的一种无创伤测量血压的方法，其特征在于利用桡动脉血压测量结果对尺动脉血压测量结果进行校准时，可将两个加压囊体连通，利用容积振动法同时在桡动脉和尺动脉测量一次血压。

21、根据权利要求 19 所述的一种无创伤测量血压的方法，其特征在于利用桡动脉血压测量结果对尺动脉血压测量结果进行校准时，将桡动脉血压测量和尺动脉血压测量分开先后相继进行。

22、根据权利要求 16 或 18 或 19 所述的一种无创伤测量血压的方法，其特征在于在长时间连续血压过程中，应自动定期地进行重新测定 Di 和 Pi；

23、根据权利要求 5 所述的一种无创伤测量血压的方法，其特征在于可采用其它判据，例如脉搏波形的形状或基线高度的变化、在脉搏波形上人为叠加上去的小振动波的振幅的变化、血流速度的变化等来判定被测动脉的无载状态；也可以采用控制液压来控制对被测动脉施加的外部压力和采用其它能够用于检测动脉脉搏的传感器来检测动脉脉搏。

24、一种无创伤测量血压的腕部探测装置，至少包括有一个由一固定装置固定于手腕桡动脉和尺动脉中的一根动脉上方的皮表上的加压囊体，其特征在于至少在桡动脉加压囊体的加压部位上设有一个动脉脉搏传感器阵列。

25、根据权利要求 24 所述的无创伤测量血压的腕部探测装置，其特征于所述的加压囊体对手腕的加压面最佳呈圆形，其直径应为手腕直径的 1/3～3/5；该加压囊体的朝向手腕的内侧壁采用具有一定弹性的薄膜做成，并使其具有向手腕方向凸出的形状，而这个囊体沿周围一圈的壁和朝向外侧的壁采用具有一定硬度的材料做成。

26、根据权利要求 24 所述的无创伤测量血压的腕部探测装置，其特征在于所述的脉搏传感器阵列中的脉搏传感器最佳是由发光器件和光电器件构成的反射式光电传感器；其最佳结构是中心部分为数个光电器件相互靠近排列成的矩形阵列，周围环绕排列发光器件；光电器件的除了朝向贴近皮肤的壁的内侧面的受光面以外的部分被用遮光材料遮盖。

27、根据权利要求 26 所述的无创伤测量血压的腕部探测装置，其特征在于所述的光电

器件阵列在平行于桡动脉和垂直于桡动脉的方向上分别至少有 2 个光电器件，其中每个光电器件分别输出一路桡动脉脉搏信号。

28、根据权利要求 26 所述的无创伤测量血压的腕部探测装置，其特征在于所述的脉搏传感器阵列最佳设置于加压囊体内部的贴近皮肤的壁的内侧面，光电器件的受光面和光电器件的发光面朝向贴近皮肤的壁的内侧面，该光电器件阵列的中心对准所述的内侧面的面积中心。

29、根据权利要求 28 所述的无创伤测量血压的腕部探测装置，其特征在于该加压囊体的朝向手腕的内侧壁的薄膜至少在传感器阵列分布的部份具有可透光性。

30、根据权利要求 24 所述的无创伤测量血压的腕部探测装置，其特征在于所述的囊体固定装置最佳为一个绑带，该绑带采用具有较高硬度和一定弹性的材料制成接近手腕直径、但在对应于手腕背侧开口的环状；它在开口处的两端应采用不可伸缩的装置加以连接。

31、根据权利要求 30 所述的无创伤测量血压的腕部探测装置，其特征在于所述的固定绑带的宽度最好大于手腕的直径，而绑带与手腕部相接触的面应具有与手腕部相吻合的凹凸形状。

32、根据权利要求 30 所述的无创伤测量血压的腕部探测装置，其特征于所述的加压囊体可与固定绑带做成一体，即采用具有一定厚度的绑带，在绑带的朝向手腕的面上对应于加压囊体的位置处加工出一个与囊体直径相同的扁平圆形凹坑，将所述的采用具有一定弹性的薄膜做成的内侧壁的边缘与绑带上的凹坑的朝向手腕的边缘密封结合。

33、根据权利要求 24 所述的无创伤测量血压的腕部探测装置，其特征在于所述的固定装置最佳还应附设有手腕固定托。所述的手腕固定托是由一定强度的硬质材料做成的托板，它的长度和宽度应保证覆盖整个手掌背侧、手腕背侧以及接近肘关节的前臂的背侧，而它的形状应将手根部的背面与手腕部的背侧面形成 100° ~175° 的夹角，并将手腕部的掌侧面相对于前臂靠近肘关节部份的手掌侧面形成 30° ~100° 的向内转角，并且最好还将手根部的中心线相对于手腕部掌侧面的中心线形成 10~40° 的朝向小拇指侧的转角。

34、根据权利要求 33 所述的无创伤血压的腕部探测装置，其特征在于所述的手腕固定托在手根部背侧面与手腕部背侧面相接处的厚度被加大，消除这部分与靠近前臂部分的直径差，并将手根部与手腕部相接部分的由于手根部向背侧弯曲而内陷的复杂形状添补成一个规则的圆柱面。

35、根据权利要求 33 所述的无创伤血压的腕部探测装置，其特征在于所述的手腕固定托的内侧面与手腕部背侧表面的凸凹形状相吻合。

36、根据权利要求 33 所述的无创伤血压的腕部探测装置，其特征在于所述的手腕固定托上设有可固定手臂和手的固定装置。

37、根据权利要求 24 所述的无创伤测量血压的腕部探测装置，其特征在于所述的动脉

脉搏传感器和加压囊体可以被在手腕部的桡动脉和尺动脉上方的皮表上分别各固定一个，由切换装置使两个加压囊体和动脉脉搏传感器交替地对桡动脉和尺动脉分别进行加压和脉搏信号检测。

38、根据权利要求 37 所述的一种无创伤测量血压的腕部探测装置，其特征在于所述的尺动脉脉搏传感器最好是两个以上在垂直于尺动脉的方向上相互靠近排列的光电器件，并且将这些光电器件相互并联从而输出一路尺动脉脉搏信号。

39、根据权利要求 24 所述的一种无创伤测量血压的腕部探测装置，其特征在于将该腕部探测装置用于测量血压时加压囊体所要连接的压力传感器也与囊体固定绑带做成一体。

40、一种采用如权利要求 24 至权利要求 39 中的任何一种腕部探测装置的无创伤测量血压的脉搏信号处理装置，其特征在于至少包括有一个上述的腕部探测装置，该腕部探测装置至少设有一个桡动脉脉搏传感器阵列，所述的脉搏传感器阵列所输出的多路脉搏信号被经放大和滤波后，连接到一个最佳脉搏信号选择装置。

41、根据权利要求 40 所述的无创伤测量血压的脉搏信号处理装置，其特征在于所述的最佳脉搏选择装置是从脉搏传感器阵列里平行于桡动脉排列的所有列传感器测得的所有列脉搏信号中振幅最大点时的振幅与其它列相比为最大的一列脉搏信号中，选出一路在囊体加压过程中具有振幅最大点、以及在囊体压力高于振幅最大点所对应的压力后具有振幅开始基本上消失并且振幅开始基本不变的点，并且其振幅最大点以及基本消失点所对应的囊体压与其它路的相比为最低的脉搏信号作为最佳脉搏信号。

42、根据权利要求 40 或 41 所述的无创伤测量血压的脉搏信号处理装置，其特征在于当所述的最佳脉搏信号被选择出后，控制一个最佳脉搏传感器位置显示装置，该装置采用直观的方式显示测得最佳脉搏信号的脉搏传感器在脉搏传感器阵列当中的具体位置。

43、根据权利要求 40 或 41 所述的无创伤测量血压的脉搏信号处理装置，其特征在于设有一个脉搏传感器位置警告装置，当测得最佳脉搏信号的脉搏传感器偏离脉搏传感器阵列的中心时会发出警告信号。

44、根据权利要求 40 所述的无创伤血压测量装置，其特征在于所述的最佳脉搏选择装置、最佳脉搏传感器位置显示装置以及脉搏传感器位置警告装置可以与腕部探测装置做成一体。

45、一种采用如权利要求 40 至 44 中任意一项权利要求所述的脉搏信号处理装置的无创伤血压测量装置，其特征在于至少包括有一上述腕部探测装置，该腕部探测装置至少设有一个桡动脉加压囊体和一个桡动脉脉搏传感器阵列，该脉搏传感器阵列输出的多路脉搏信号经最佳脉搏选择装置选出一路桡动脉的最佳脉搏信号，所述的桡动脉加压囊体与一个供压－测量装置的电压／压力转换器的压力输出端以及压力传感器的压力输入端相连接，最佳脉搏选择装置输出的桡动脉最佳脉搏信号与该供压－测量装置的脉搏振幅检测装置的

信号输入端相连接。

46、根据权利要求 45 所述的无创伤血压测量装置，其特征在于所述的供压－测量装置可基于容积振动法间断地测量桡动脉的平均压、收缩压以及舒张压。

47、根据权利要求 45 所述的无创伤血压测量装置，其特征在于所述的供压－测量装置可基于容积补偿法连续地测量桡动脉的血压波形。

48、根据权利要求 45 所述的无创伤血压测量装置，其特征在于可利用切换装置使得所述的供压－测量装置交替地基于容积振动法和容积补偿法以分别测量桡动脉的平均压、收缩压以及舒张压或血压波形。

49、根据权利要求 45 至 48 所述的任意一种无创伤血压测量装置，其特征在于所述的腕部探测装置具有两个相互独立的动脉脉搏传感器和两个相互独立的加压囊体，以及两个相互独立供压－测量装置，由切换装置交替地使用它们对桡动脉和尺动脉进行间断的或连续的血压测量。

50、根据权利要求 49 所述的无创伤血压测量装置，其特征在于所述的尺动脉脉搏传感器采用数个相互并连的光电器件，它们输出的一路尺动脉脉搏信号经过放大和滤波后可以直接与用于测量尺动脉血压的供压－测量装置中的脉搏振幅检测装置的信号输入端相连接。

51、根据权利要求 49 所述的无创伤血压测量装置，其特征在于可将对桡动脉和尺动脉进行血压测量的两个相互独立的供压－测量装置中的除了脉搏信号放大·滤波、最佳脉搏信号选择以及脉搏振幅检测部分以外的其它部分共用一个。

52、根据权利要求 49 至 51 所述的任意一种无创伤血压测量装置，其特征在于用于对桡动脉和尺动脉进行血压测量的供压－测量装置可以完全共用一个供压－测量装置，而在对桡动脉和尺动脉中的某一根动脉进行血压测量时，通过一个切换装置将上述的供压－测量装置交替地与被测动脉上的加压囊体管道以及脉搏信号输出端相连接。

53、根据权利要求 49 或 50 所述的无创伤血压测量装置，其特征在于最好设置一个利用桡动脉血压测量结果对尺动脉血压测量结果进行校准的装置。

54、根据权利要求 49 所述的无创伤血压测量装置，其特征在于所述的最佳脉搏选择装置、最佳传感器位置显示装置、传感器位置警告装置以及供压－测量装置可以与腕部探测装置做成一体。

55、根据权利要求 49 或 54 所述的无创伤血压测量装置，其特征在于可将所述的无创伤血压测量装置与血压测量结果记录装置做成一体。

56、根据权利要求 49 或 54 或 55 所述的无创伤血压测量装置，其特征在于可将所述的无创伤血压测量装置与其它生理参数的测量记录装置做成一体。

57、根据权利要求 49 或 54 至 56 中所述的任意一种无创伤血压测量装置，其特征在于可将所述的无创伤血压测量装置与通讯装置相连接。

说　明　书

无创伤测量血压的方法和装置

本发明涉及测量血压的方法和装置，尤其涉及一种所谓容积振动法的无创伤间断测量人体动脉血压的方法和装置以及一种所谓容积补偿法的无创伤连续测量人体动脉血压的方法和装置。

容积振动法(也称“容积示波法”)利用了当血管外压力等于血管内平均压和高于血管内收缩压时,其血管分别处于顺柔性最好的状态(该状态被称为“无载状态”)和被压扁的原理。由于动脉血管内的血压时刻都在随着心脏搏动做周期性变化(每一心动周期中的血压的最高值称为收缩压,最低值称为舒张压,平均值称为平均压),而血管的直径(容积)又在随动脉内的血压的周期性变化形成脉搏。显然,当血管外压力等于血管内平均压,即血管处于顺柔性最好的状态时脉搏的振幅最大,而当血管外压力高于血管内收缩压,即血管被压扁时脉搏消失。利用容积振动法测量动脉血压时,一般首先在被测动脉上方的皮肤表面上固定一个用于对动脉进行外部加压的气囊（或液囊）和一个用于检测动脉脉搏的光电传感器,然后使得气囊压力在一个下限低于平均压、上限高于收缩压的范围内以大约 3 mmHg／秒的速度做一次线性的或阶梯性的升压或减压,同时测量整个气囊压力变化过程中的脉搏的振幅的变化。如果能保证在气囊中心下面的软组织中气囊压力被不衰减地传递到动脉外表面，而且光电传感器也仅仅检测位于这部分软组织中的动脉的脉搏,则脉搏振幅最大点和消失点时的气囊压力将分别等于动脉中的平均压和收缩压。因而利用压力传感器测出这两个时刻的气囊压力值，即可无创伤地测量出动脉中的平均压和收缩压;另外,利用测得的平均压和收缩压还可以按照经验公式，即舒张压＝(3×平均压－收缩压)／2计算出舒张压。由于每一个气囊加压或减压过程都需要一定的时间,而每一个过程只能测出一次血压值,故利用这种方法只能进行间断的血压测量。该方法与传统的无创伤间断测量血压的听诊法（也称柯氏音法）、触诊法、 发红法以及超声波多普勒法相比,分别具有能够测量平均压,避免主观判断能力差别造成的测量误差，以及装置的构造和使用简单等优点。另外,它与现在已被广泛应用于临床和家庭的压力振动法（也称示波法）相比,也具有能够准确测量而不是根据统计数据推算收缩压的优点。

容积补偿法(也称“血管无载法”) 则利用了血管外压力在任何时刻都与血管内血压相等时，血管直径将不再随血管内血压波形变化(即不再搏动)而被嵌定在其无载状态时的直径上的原理。这种方法一般也包括一个用于对动脉进行外部加压的气囊（或液囊）和一个用于检测动脉脉搏的光电传感器,另外还具有一个用于将检测到的动脉脉搏去控制气囊压力

的反馈控制系统。在利用容积补偿法连续测量血压时，首先和容积振动法一样，在一定的范围内改变气囊压力，同时测量脉搏的振幅随气囊压力的变化。当气囊压力等于动脉内的平均压、亦即使得动脉血管处于最柔软的状态、脉搏振幅呈现最大值时，接通反馈控制系统将检测到的动脉脉搏信号进行放大和相位补偿，并用它去进一步控制气囊的压力在平均压的基础上按照脉搏波形变化。一旦使得加在被测动脉血管壁外部的压力波形不仅在形状上、而且在幅值上都与该动脉内的血压的周期性变化的波形完全相同，亦即使得被测动脉血管壁的内外两侧的受力在任何时刻都达到动态平衡时，被测动脉的血管直径将不再随血管内血压波形变化而被嵌定在其无载状态时的直径上，即脉搏振幅接近为零。这时只要用压力传感器连续测出气囊的压力值，即可实现连续的血压波形和血压值的测量。由于无创伤，该方法与传统的有创伤连续测量血压的动脉内插管直接测压法相比，具有无痛苦，不会引起出血、感染、血栓形成、栓塞以及神经损伤等并发症或后遗症，以及操作被极大地简单化等优点。另外，它与近年来出现的张力法（也称反力法）相比，也具有无需校准，测量结果不易受病人体动干扰的影响等优点。

上述两种方法目前没有被用在通常用于测量血压的上臂，而一般被用在手指上来测量手指动脉血压。这主要是因为上臂部位的肱动脉位置较深，不但不易进行光电脉搏检测，而且必须对上臂进行全周或接近全周的加压才能充分地压迫肱动脉。由于有这种压迫，长时间地频繁使用容积振动法间断测量血压或者长时间地持续使用容积振动法连续测量血压，都会使得其下游的整个前臂和手部的血液循环和神经机能受到严重的影响；而手指动脉位置表浅，便于实现光电脉搏检测，同时测量时气囊加压对血液循环和神经机能的影响也较小。但大量的临床实验结果已经表明这两种方法用于手指上也存在另一个重大的问题，即由于手指动脉属于对血流阻力大的末梢小动脉，其血压与一般临床上判断病人血压是否正常时所用的所谓“全身血压”（即靠近心脏的大动脉的血压）相比，即使在正常情况下也要低 10 mmHg 左右，若在动脉硬化情况下这个差可达数十 mmHg。更重要的是由于小动脉血管壁中的平滑肌成份比大动脉血管壁中的大，而这些血管平滑肌成份极易受各种因素（比如寒冷、麻醉等）的影响产生收缩或舒张，造成小动脉中血压大幅度波动，以至于在许多场合用手指动脉测得的血压值根本不能被用来反映病人全身血压。尤其当遇到病人的循环功能很差的场合，手指动脉有时会因血管平滑肌极度收缩造成动脉内失血，以至于在手指上无法测量血压。

为了既能正确地反映人体的全身血压，又能不影响被测部位下游的血流循环，近年来，有人提出了一种把这两种方法的测量部位改到手腕部，并且将传统的全周加压气囊改为一个小面积的局部加压气囊从而仅仅压迫手腕两根动脉（挠动脉和尺动脉）中的一根动脉的方案。

这是基于两点考虑：其一是挠动脉或尺动脉的直径远大于手指动脉的，而且它们的血管壁中的平滑肌成份少于手指动脉中的，故它们的血压比手指动脉和颞动脉的更接近人体全身血压，受各种因素的影响也要小的多。并且即使是在病人的循环功能很差的场合，在挠动脉或尺动脉上一般也总能测出脉搏，而不会出现血压测量无法进行的情况。特别是，由于手腕动脉的上述特点以及在手腕部便于操作等原因，手腕部位的挠动脉有创直接测压多年来一直被世界各国作为最常用的血压测量方法应用于手术和危重病监护，以至于手腕动脉的血压值已被临床医务人员习惯作为最可靠、最准确的人体全身血压的判据。因而把这两种方法的测量部位改到手腕部具有极高的临床使用价值。 其二是正常人在手腕处较大的动脉和静脉都在两根以上，其中两根动脉（挠动脉和尺动脉）在手掌内部被通过两个动脉弓相互连通，数根静脉在手的背部也被通过手背静脉网相互连通。这些血管之间的相互连通保证了既便使手腕部的某根动脉或／和部分静脉被长时间阻断，但另一根动脉和其他大部分的静脉仍能血流畅通时，手部的血液循环也基本上不会受到影响。因而，在手腕挠动脉和尺动脉中的一根动脉上可以长时间地利用这两种方法进行频繁或连续的血压测量。

然而，虽然有关的研究已经表明，在桡骨末端朝向掌侧的最高凸起点附近的桡动脉上，利用容积振动法和容积补偿法，可以分别准确地测得平均压、收缩压或血压波形，但这些研究也发现，要在手腕部准确测量这些血压值实际上是非常困难的。主要表现为血压测量精度对于光电传感器的位置非常敏感，即便是在桡骨末端朝向掌侧的最高凸起点处，在相互之间仅仅相差 2 、3 mm 的不同位置上，测得的血压值就会有很大的不同。另外，其测量精度还受一些外部因素的影响：一是当手腕部以前臂的长轴为转动轴进行转动，或当手根部相对于手腕做向手掌侧或手背侧的弯曲时，都会使测得的血压值发生很大的变化。 二是在随着气囊加压，除了气囊外壁会沿手腕半径方向向外移动以外，气囊整体还会发生沿圆周方向向手腕掌侧中心部以及沿长轴方向向手根部的移动。这些移动都会改变气囊的容积，而且圆周方向以及长轴方向的移动还会引起光电传感器的位移。 其中光电传感器的位移会对容积振动法和容积补偿法的测量精度都造成影响，而气囊容积的改变则特别影响容积补偿法的精度，甚至破坏其反馈控制系统的稳定性。另外，长时间的连续测量后还会出现气囊固定的松动，这也明显影响容积补偿法的精度和反馈控制系统的稳定性。另一方面，这些研究还发现，由于气囊的固定绑带也会对手腕的其它部位产生较大的压力，所以进行长时间连续测量后，位于气囊下游的手部的血流循环和神经机能仍会受到较大的影响。特别是，气囊的长时间持续压迫会造成气囊压迫部位的疼痛。

本发明的目的是提供一种无创伤连续测量血压的方法和装置，它能利用容积振动法和容积补偿法原理很简单地、并且不受上述外部因素的影响地在手腕部正确地测量间断和连

续的桡动脉或／和尺动脉血压，同时还能消除长时间连续测量对手部的血流循环和神经机的影响。

为达到上述目的，本发明采用的解决方案是：

1．至少将手根部相对于手腕部的夹角定位于最适合测量桡动脉血压的角度上，另外，最好还将手腕部相对于前臂的转角定位于最适合测量桡动脉血压的角度上。这两个角度的配合定位可保证降低桡动脉两旁的肌腱和神经的位置，使得桡动脉处于一个与其下方的桡骨距离最近的位置，有利于气囊有效地压迫桡动脉。在长时间频繁或连续测定血压时，为保证腕部测量定位，本发明还可采用一个手腕固定托来固定手腕部的转动和手根部的弯曲，以便在被测者出现体动时，加压气囊和脉搏传感器相以及手腕内部的肌腱、神经和桡骨相对于挠动脉的位置始终保持不变；

2．为了很容易地找到能够最准确地测量桡动脉血压的精确位置，在位于桡骨末端朝向掌侧的最高凸起点上方皮表上的桡动脉加压囊体的加压面积中心设置一个脉搏传感器阵列。在对囊体加减压时，由脉博传感器阵列从手腕部多个位置上测量出整个囊体压力变化过程中的桡动脉波信号，并送到最佳脉搏信号选择电路。因为离桡动脉近的传感器测得的脉搏信号振幅大，而压力传递好的位置测得的脉搏信号平均压和收缩压低，为了找到桡动脉上压力传递最好的点，这个最佳脉搏信号选择电路从阵列里平行于桡动脉排列的所有列传感器测得的所有列脉搏信号中振幅最大点处的振幅与其它列的相比为最大的一列脉搏信号中，选出一路在囊体加压过程中具有振幅最大点、以及在囊体压力高于振幅最大点所对应的压力后具有振幅开始基本上消失并且振幅开始基本不变的点，并且其振幅最大点以及基本消失点所对应的气囊压与其它路的相比为最低的脉搏信号作为最佳脉搏信号，将其用于容积振动法或容积补偿法测量桡动脉血压。为了将压力传递深度最大的囊体中心对准所选出的能够最准确地测量桡动脉血压的精确位置，在选出最佳脉搏信号后，用最直观的方式显示出测得该最佳脉搏信号的传感器位于传感器阵列的哪个位置，然后调节气囊的固定位置使测得该最佳脉搏信号的传感器位于传感器阵列的中心。另外，在进行长时间血压测量时，为了防止因被测者的体动造成测量位置的偏移，应定期自动地检查最佳传感器位置是否位于阵列的中心，如果发现偏离中心过大，应发出警告信号以便重新调整加压囊体的固定位置；

3．使手根部向小拇指侧转动的转动一个小的角度，以便使得大拇下方的手根凸起部远离桡骨末端朝向掌侧的最高凸起点而不至于妨碍采用直径较大的气囊的固定绑带在这个部位贴紧手腕；

4．为了防止气囊加压时发生的气囊整体沿手腕长轴方向向手根部移动，有利于气囊

绑带的稳固，应消除手根部与手腕部相接的部分与靠近前臂部分的直径差，同时将这部分的由于手根部向背侧弯曲而内陷的复杂形状添补成一个规则的圆柱面；

5．为了减小囊体加压时对手腕部其它部分的压力，使得囊体的固定装置以及手腕的固定装置与手腕部有尽可能大的接触面积；

6．为了避免由于长时间持续压迫一处造成的疼痛和麻木，可在桡动脉和尺动脉上分别各设一个加压囊体，从而在两根动脉上交替地进行血压测量。由于在尺动脉上难以测准血压，可以利用桡动脉血压测量结果对尺动脉血压测量结果进行校准。即求出同时或相继测得的桡动脉的平均压与测得的尺动脉脉搏振幅最大点所对应的囊体压力的差 Di，同时求出测量尺动脉压的过程中，囊体压力等于桡动脉的收缩压时的尺动脉脉搏振幅与其最大振幅的比例 Pi。这样，在后面再测量尺动脉血压时，每次将新测得的尺动脉脉搏振幅最大点所对应的囊体压力减去 Di，得出这次的平均压；同时，在体囊压力低于这次的平均压的范围内找到尺动脉脉搏振幅中与其最大振幅成比例 Pi 的点所对应的囊体压力，得出这次的收缩压。为了防止被测腕部有过大的转动改变了 Di 和 Pi，在长时间测量血压过程中，应自动定期地用同样的方法重新测定 Di 和 Pi。

附图的简要说明

图 1 是本发明的第一个实施例的总框图；

图 2 是图 1 所示的实施例中的整个腕部探测装置的示意图；

图 3 是图 2 的腕部探测装置在与手腕垂直的方向上、沿腕部探测装置中的外部加压气囊的正中所做的横断面图；

图 4 是沿图 3 的腕部探测装置上的 A－A 剖面线所做的、反映加压气囊内脉搏传感器构造的剖面图；

图 5 是利用图 2 的腕部探测装置中的手腕固定托将手腕部和手根部固定成的三个角度的示意图；

图 6 是图 1 所示的实施例测量平均压和收缩压的方法的示意图；

图 7 是本发明的第二种实施例的总框图；

图 8 是第二种实施例测量血压波形的方法的示意图；

图 9 是本发明的第三种实施例的总框图。

图 10 是本发明的第四种实施例的腕部探测装置在与手腕垂直的方向上、沿腕部探测装置中的外部加压气囊的正中所做的横断面图。

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实施本发明的方式:

实施例 1

本发明的实施例 1 是一种在手腕部利用容积振动法无创伤间断测量血压的方法。

首先，本实施例的测量定位方法，如图 5 所示，将手根部 17 相对于手腕部 18 的夹角固定在最适合测量桡动脉血压的角度上，使它们最好形成 100～175° 的夹角；并进一步将手腕部 18 相对于前臂 19 的转角固定在最适合测量桡动脉血压的角度上，该转角最好为 30～100°。该两个角度的配合定位可保证降低桡动脉两旁的肌腱和神经的位置，使得桡动脉处于一个与其下方的桡骨距离最近的位置，有利于气囊有效地压迫桡动脉。

在长时间频繁或连续测定血压时，为保证腕部测量定位，如图 2 所示，本发明还可采用一个手腕固定托 6 来固定手腕部 18 的转动和手根部 17 的弯曲，以便在被测者出现体动时，加压气囊 5 和脉搏传感器阵列以及手腕内部的肌腱、神经和桡骨相对于挠动脉的位置始终保持不变；

由上述方法进行定位后，本实施例的无创伤测量血压的方法，如图 1 和图 6 所示，包括有以下步骤：

A、至少在手腕部桡骨 7 末端朝向掌侧的最高凸起点处的皮肤表面上设置一个动脉脉搏传感器阵列 4 和一个加压囊体 3，并保持传感器阵列和囊体相对于该点的位置不变；

B、此时控制加压囊体 3 压力在下限低于被测者可能的平均压、上限高于被测者可能的收缩压的范围内进行变化。在囊体 3 压力变化时，仅仅囊体 3 靠近手腕一侧的面发生仅朝向手腕、并且不产生周向张力的变形，同时不发生任何方向的位移；

C、在囊体 3 压力变化的同时，由脉搏传感器阵列 4 从手腕部多个位置上测量出整个压力变化过程中的桡动脉波信号，并送到最佳脉搏信号选择电路 28；由于离桡动脉近的传感器测得的脉搏信号振幅大，而压力传递好的位置测得的脉搏信号平均压和收缩压低，为了在桡动脉 7 上方找到压力传递最好的点，从阵列里平行于桡动脉排列的所有列传感器测得的所有列脉搏信号中振幅最大点处的振幅与其它列相比为最大的一列脉搏信号中，选出一路在囊体加压过程中具有振幅最大点、以及在囊体压力高于振幅最大点所对应的压力后具有振幅开始基本上消失并且振幅开始基本不变的点(如图 6 所示)，并且其振幅最大点以及基本消失点所对应的囊体压力与其它路的相比为最低的脉搏信号作为最佳脉搏信号。

D、将选出的最佳脉搏信号用于无创伤地测量桡动脉血压。在本实施例中，将选出的最佳脉搏信号用于容积振动法无创伤测量平均压和收缩压。

在本实施例中，动脉脉搏传感器阵列 4 最好位于加压囊体 3 的面积中心，使压力传递

最好的位置测得的最佳脉搏信号的传感器位于传感器阵列 4 中心时，压力传递深度最大的加压囊体 3 的面积中心正好能对准这个压力传递最好的位置。

选出最佳脉搏信号后，用最直观的方式显示出测得最佳脉搏信号的传感器位于传感器阵列的哪个位置上。在固定囊体 3 时，根据这个显示来调节囊体 3 的位置，使得最佳传感器位置尽可能正好位于传感器阵列 4 的中心，压力传递深度最大的囊体的面积中心位于压力传递好的位置上；

本实施例在应用于长时间血压测量时，可自动地检查最佳传感器位置是否位于阵列 4 的中心，当偏离中心过大时，发出警告信号，重新调整加压囊体 3 的固定位置。

本实施例中将动脉脉搏传感器阵列 4 固定在囊体的朝向手腕的壁的内侧面，以便不影响囊体内侧壁均匀地压迫手腕表面，又能直接从桡动脉 7 探测脉搏信号。

在测量桡动脉血压时，最好还应将手根部 17 的中心线相对于手腕部 18 掌侧面的中心线向小拇指侧转动的转角固定呈 10～40° 的，使得大拇指下方的手根凸起部 20 不妨碍囊体 3 的固定绑带贴紧手腕，如图 5b 所示。

为了防止囊体 3 加压时发生的囊体 3 整体沿手腕长轴方向向手根部移动和有利于囊体固定绑带的稳固，本实施例消除手根部 17 与手腕部 18 相接部分与靠近前臂 19 部分的直径差，同时将这部分的由于手根部 17 向背侧弯曲而内陷的复杂形状添补成一个规则的圆柱面。

囊体 3 的固定装置 5 以及手腕的固定装置 6 与手腕部有尽可能大的接触面积，以尽可能减小囊体 3 加压时囊体固定装置 5 对手腕部 18 其它部分的压力。

如图 1 所示，为实现本实施例方法，本实施例所采用的装置包括三大部分，其中第一部分是一个用于对腕部桡动脉 7 进行脉搏检测和外部加压的腕部探测装置 0；第二部分是一个用于对腕部探测装置 0 测得的桡动脉脉搏信号进行最佳脉搏选择的脉搏信号处理装置 1；第三部分是一个用于供给气囊 3 压力并测量气囊压力和桡动脉脉搏从而测量桡动脉血压的供压－测量系统 2。

首先对第一部分　　腕部探测装置 0 进行说明。如图 2 和图 3 所示，在本实施例是对手腕部的挠动脉 7 进行脉搏波检测和外部加压，从而实现挠动脉的血压测量的。这个腕部探测装置 0 包括挠动脉加压气囊 3，动脉脉搏传感器 4，气囊固定绑带 5 以及手腕固定托 6 共四个部分。

如图 2 和图 3 所示，在本实施例中的挠动脉加压气囊 3 是一个扁平的圆形气囊。为了保证这个气囊的压力能充分地传到挠动脉 7 所在的深度，一方面，这个气囊 3 的固定位置应使得它的中心能够对准桡骨 8 末端朝向掌侧的最高凸起点处的桡动脉 7；另一方面，这个气囊 3 的直径应充分地大，但过大会同时压迫到另一根尺动脉 9 和其他静脉血管，故这个

直径可选为手腕直径的 1/3～3/5（例如对于成人一般可选在 30 mm 左右）。另外，为了保证这个气囊 3 在充气后不至于因膨胀而在它的壁中产生周向张力而影响对挠动脉 7 的有效压迫，这个气囊 3 的朝向内侧（手腕）的壁 10 采用可透光的、具有一定弹性的薄膜 10 做成，并使其具有向手腕一侧凸出的形状，而这个气囊 3 的沿圆周一圈的壁和朝向外侧的壁采用具有一定硬度的材料做成。

挠动脉脉搏传感器 4 是一个反射式光电传感器阵列。如图 3 所示，手腕部的内部具有复杂的非匀质构造。仅就桡动脉 7 附近而言，除了桡动脉 7 的下方有桡骨 8 以外，桡动脉两旁的软组织当中还含有数根硬度相当高、对软组织中的压力传递起阻碍作用的肌腱 11 和神经 12。按照力学原理，能够最有效地将气囊压力传递到桡动脉 7，从而精确测量桡动脉血压的部位是桡动脉 7 离表皮和桡骨 8 最近，而离两旁的肌腱 11 和神经 12 最远的点。但是在实际的手腕内部（见图 1，图 3），桡动脉 7 本身的深度、位置以及这些肌腱 11 和桡骨 8 的形状、位置都随着轴向位置的不同而不同，特别是桡骨 8 朝向掌侧的最高突起点所在的桡骨端头的横断面形状也是不规则的，而且因人而异。显然要找到上述能够精确测量桡动脉血压的最佳点必须采用传感器阵列 4 进行精细的多点测量后进行分析比较。为了便于将该传感器 4 与上述气囊 3 一起固定到手腕上，并且不影响气囊内侧壁 10 均匀地压迫手腕表面，这个传感器阵列 4 被内藏在上述气囊 3 的内部。如图 4 所示，在本实施例中，这个传感器阵列 4 由 10 个红外发光二极管 13 和 15 个光电三极管 14 构成。其中，15 个光电三极管 14 组成一个矩形阵列。这个阵列在与桡动脉 7 的走行相平行的方向上为 3 列，每列为 5 行。列与列以及行与行之间均设有间隙。另外，10 个红外发光二极管 13 距离光电三极管矩阵的 4 个边之间均设有间隙，环绕排列在矩阵的四周。这些发光二极管 13 和光电三极管 14 被固定在上述气囊 3 的用半透明薄膜做成的内侧壁 10 的内表面。固定时，应使得发光二极管 13 的发光面和光电三极管 14 的受光面朝向薄膜内侧壁 10 的内表面，并使得光电三极管阵列的中点对准薄膜内侧壁 10 的中心。另外，为了防止发光二极管 13 发出的光以及外界光线直接被光电三极管 14 接收，发光二极管 13 和光电三极管阵列之间以及整个光电传感器的周围都贴有一层伸展性好的遮光薄片 15（如黑色海棉片）。在用该光电传感器检测挠动脉 7 的脉搏时，其中的 10 个发光二极管 13 发出的红外光从不同的方位透过气囊 3 的用半透明薄膜作成的内侧壁 10 射入手腕内部。由于挠动脉 7 随其中血压的周期性变化所产生的血管容积变化会造成反射到光电三极管 14 中的光强度变化，进而使光电三极管 14 的输出电流产生变化，由此 15 个光电三极管 14 便会将从 15 个位置的挠动脉 7 的容积变化转换成 15 路挠动脉脉搏信号输出。

气囊固定绑带 5 被用来把内藏有脉搏传感器 4 的加压气囊 3 固定在上述的手腕位置上。

实际上，为了简化结构，本实施例把气囊 3 与绑带 5 做成了一体，即采用有一定厚度和硬度的绑带，在其朝向手腕的面的对应于气囊的位置上加工出一个直径与气囊 3 直径相同的扁平圆坑，然后把上述用薄膜做成的气囊内侧壁 10 的边缘粘合在绑带 4 的凹坑的朝向手腕的边缘上，从而利用这个用薄膜做成的气囊内侧壁 10 和绑带 5 上这个具有一定硬度的空腔构成上述的气囊 3。为了防止气囊 3 充气时气囊外壁沿手腕半径方向的移动，这个绑带 5 应由基本上不可伸缩的材料制成，而且它的两端的固定也应采用具有不可伸缩性的装置。在本实施例中，这个绑带 5 的两端被利用尼龙搭扣 16 固定在手腕固定托 6 上。同时，为了防止气囊充气时气囊 3 整体沿圆周方向的移动，这个绑带 5 在整体上（至少在以气囊为中心的从桡骨 8 背侧到尺骨掌侧的部分）都应具有一定的硬度。这是由于气囊 3 整体沿圆周方向移动的原因是手腕在横断面上呈椭圆，而对桡动脉 7 加压的气囊 3 是一个局部加压气囊，并且它正好处于两个不同曲率的弧的相接之处。这必然造成当气囊加压时，固定气囊的绑带 5 中的拉力中的周向分力在气囊两侧不平衡，使气囊 3 产生周向移动。但是这种移动的同时会伴随着绑带 5 的形状的变化，因而使绑带 5 不易变形可以阻止这种移动 。另外，这个绑带 5 的材料还应具有一定的弹性，以便当手腕在受到长时间连续压迫后直径变小时，其回弹性能还能使得它能把气囊 3 紧固在手腕上而不会发生松动。另一方面，为了保证仅由气囊 3 充分压迫被测的桡动脉 7，而尽可能地减小绑带 5 对手腕其他部分的压强，这个绑带 5 与手腕的有效接触面积应尽可能地大，为此应采用尽可能大的绑带宽度（对于一般成人最好大于 50 mm），并使得绑带 5 在与手腕部 18 和手根部 17 相接触的部分都具有于手腕部和手根部的外形相吻合的凹凸形状。

手腕固定托 6 是具有一定强度的硬质材料做成的托板，它的长度和宽度应保证覆盖整个手掌背侧、手腕背侧以及接近肘关节的前臂的背侧。 该固定托 6 具有三个作用：第一个作用是被用来将手根部 17 相对于手腕部 18 的夹角和手腕部 18 相对于前臂 19 的转角分别固定在最适合测量桡动脉血压的角度上，同时限定手腕部 18 的转动和手根部 17 的弯曲，以便以尽可能地使得被测者出现体动时，加压气囊 3 和脉搏传感器 4 以及手腕内部的肌腱 11、神经 12 和桡骨 8 相对于桡动脉 7 的位置始终保持不变。 如图 5(a)和图 5(c)所示，手腕固定托 6 的形状应使得手根部 17 的背侧面与手腕部 18 的背侧面形成 100～175° 的夹角，并使得手腕部 18 的掌侧面相对于前臂靠近肘关节部分 19 的掌侧面形成 30～100° 的向内的转角。保证这两个角度可以降低桡动脉 7 两旁的肌腱 11 和神经 12 的位置，并使得桡动脉 7 处于一个与其下方的桡骨 8 距离最近的位置，有利于气囊 3 有效地压迫桡动脉 7。另外，如图 5(b)所示，固定托 6 的形状还应使手根部 17 的中心线相对于手腕部 18 掌侧面的中心线形成 10～40° 的向小拇指侧转动的转角，以使得大拇下方的手根凸起部 20 远离桡骨末端朝向

掌侧的最高凸起点而不至于妨碍采用直径较大的气囊的固定绑带 5 在这个部位贴紧手腕。手腕固定托 6 的第二个作用是有利于气囊绑带 5 的稳固。考虑到气囊 3 加压时发生的气囊整体沿手腕长轴方向向手根部 17 移动的原因是由于手腕部 18 在接近前臂 19 处的直径大于接近手根部 17 处的直径，导致当气囊 3 加压时在其外侧壁上会产生朝向手根部 17 的分力所造成的，因而应如图 5(a)所示加大该托板 6 在手根部 17 背侧面与手腕部 18 背侧面相接处的厚度，以消除这部分与靠近前臂 19 部分的直径差。另外，这个部分的加厚还可以加大该托板固定手根部 17 时的强度，同时将手根部 17 与手腕部 18 相接部分的由于手根部向背侧弯曲而内陷的复杂形状添补成一个规则的圆柱面，便于较宽的气囊绑带 5 的固定。手腕固定托 6 的第三个作用是分散气囊绑带 5 对手腕背侧的压力。因而应保证它的内侧面能很好地与手腕部 18 背侧的凸凹形状相吻和，（因此，为了适应不同形状、粗细的手腕，须分别做几种固定托备用），并且为避免固定托 6 过硬造成被测者不舒适，可在固定托 6 的内侧面粘一层薄的软衬垫 21。另外，在这个手腕固定托 6 上固定有几根末端设有尼龙搭扣的小绑带 22 用于将被测者的手根部 17、手腕部 18 以及前臂 19 绑在这个手腕固定托中。

本实施例的无创伤间断挠动脉血压测量的工作原理是：

如图 1 所示，该腕部探测装置 0 的脉搏传感器阵列 4 的 15 路输出分别与脉搏信号处理装置 1 中的 15 通道脉搏信号放大·滤波电路 23 的 15 个输入端相连接，同时把该腕部探测装置 0 中挠动脉加压气囊 3 的的导气管与供压－测量系统 2 中的电压／气压转换器 24 的压力输出端以及压力传感器 25 的压力输入端相连接。压力传感器 25 的输出端接到压力信号放大电路 26。

固定腕部探测装置时，首先将被测者的手根部 17、手腕部 18 以及前臂 19 固定在腕部探测装置 0 中的手腕固定托 6 中，然后在把腕部探测装置 0 中的气囊 3 的中心对准桡骨末端朝向掌侧的最高凸起点处的桡动脉 7 后，将气囊固定绑带 4 缠绕在手腕部 18，并将固定绑带的两端利用尼龙搭扣 16 与手腕固定托 6 固定在一起。

血压连续测量开始时，供压－测量系统 2 中的气囊压力设定电路 27 开始自动地调节供给电压／气压转换器 24 的电压，使腕部探测装置 0 中的气囊 3 开始对挠动脉 7 进行外部加压，同时腕部探测装置 0 中的脉搏传感器阵列 4 从 15 个位置检测出挠动脉脉搏信号，送到脉搏信号处理装置 1 经放大·滤波后再送到其中的最佳脉搏信号选择电路 28。由于位置不同，从 15 个位置检测出挠动脉脉搏信号的振幅以及包络线形状都是相互不同的，并且可能在某些位置检测出挠动脉脉搏找不到最大点和消失点。显然，测得的脉搏信号在振幅最大点时的振幅比其它列大的列离动脉近；测得的平均压和收缩压比其它行低的行位于压力传递好，即能够准确测量血压的位置。因而在振幅最大点的振幅最大的列中，选出一路在囊体加压过

程中具有振幅最大点、以及在囊体压力高于振幅最大点所对应的压力后具有振幅开始基本上消失并且振幅开始基本不变的点，并且其振幅最大点以及基本消失点所对应的囊体压力与其它路的相比为最低的一路脉搏信号作为最佳脉搏信号。

被选出的最佳脉搏信号被送到振幅最大点·消失点检测电路 29。按照容积振动法的原理(图 6),这两个点出现时的气囊压力即分别等于动脉内的平均压和收缩压。所以当检测电路 29 检测到振幅最大点和消失点时,给出控制信号,使压力值输出电路 30 输出那两个时刻的气囊压力值,即测出了平均压和收缩压。然后还可以再通过舒张压计算部分 31 按照舒张压 = (3 × 平均压 - 收缩压) / 2 计算出舒张压。

另一方面,为了便于定位，被选出的最佳脉搏信号还被送去进行最佳传感器位置显示。这个显示可以在血压测量结果显示器上用最直观的方式(例如画出所用的传感器阵列)显示出测得最佳脉搏信号传感器位于传感器阵列的哪个位置上。在固定气囊 3 时，应根据这个显示来调节气囊 3 的固定位置,尽可能使得最佳传感器位置正好位于阵列的中心。在本实施例中，还设有一个脉搏传感器位置报警电路 38,如果固定气囊时或长时间血压测量过程中被测的手腕有较大的转动(虽然手腕固定托 6 能起到限制手腕部 18 相对于前臂 19 的转动的作用,但实际上手腕部还可以做一定的转动)出现最佳传感器位置偏离阵列的中心过大时，该报警电路 38 会报警提醒重新固定气囊 3。由于每次测量中都进行最佳脉搏信号选择,因此可以保证每次都在最佳点测量血压。

该实施例特别适用于需要长时间测量血压，但血压变化比较平缓（例如手术后的复苏、治疗后的恢复等）的病人的临床或家庭监护。

实施例 2

作为本发明的第二个实施例是一个在手腕部利用容积补偿法无创伤连续测量桡动脉血压的方法和装置。如图 7 所示，本实施例的测量定位以及测量方法与实施例 1 相同，其主要区别在于将选出的最佳脉搏信号用于容积补偿法无创伤连续测量挠动脉血压波形。由于容积补偿法是一种已有技术，其工作过程在后面的说明中进行详细描述。

本实施例的装置请参见图 7，其中的腕部探测装置 0 和脉搏信号处理装置 1 都可采用与实施例 1 的相同的装置;另外,手腕固定托和气囊的固定方法也与实施例 1 的相同,在此不再重复地说明。在本实施例中,与实施例 1 相比的主要区别是供压 - 测量系统 32 中的最佳脉搏信号选择电路 28 的输出端不是被用去控制压力值输出电路 30 读出气囊 3 的压力值，而是被与电压 / 气压转换器 24 的控制信号输入端连接成了一个闭环的反馈控制系统用来控制气囊 3 中的压力的变化。

在利用这种方法和装置进行连续血压测量之前，为了找到并记下被测的挠动脉 7 在无载状态时的容积，供压－测量系统 32 首先把工作状态开关 33 接到“开环”位置。如图 8 所示，在这个开环工作状态下，也和容积振动法一样，供压－测量系统中的气囊压力设定电路 27 自动地调节供给电压／气压转换器 24 的电压，使腕部探测装置 0 中的气囊 3 开始对挠动脉 7 进行外部加压，同时腕部探测装置 0 中的脉搏传感器阵列 4 从 15 个位置检测出挠动脉 7 的脉搏信号，经放大·滤波后送到最佳脉搏信号选择电路 28。被选出的最佳脉搏信号送到振幅最大点检测电路 34。当振幅最大点被检测到，即识别出桡动脉 7 已是在该血管无载状态容积的上下随动脉内的血压的周期性变化而搏动时，系统会使气囊压力设定电路 27 停止它对气囊 3 的压力调节，并使得一个无载容积记忆电路 35 记下这时挠动脉脉搏波形的平均值（直流成份）作为被测者挠动脉的无载状态容积 Vo。

然后，供压－测量系统 32 自动地把工作状态开关 33 接到“闭环”位置，把脉搏传感器检测到的挠动脉 7 在这个无载状态容积附近的脉搏与被无载容积记忆电路 35 记下来的无载容积 Vo 通过一个比较电路 36 相减，并逐渐增加伺服放大电路 37 的增益，将得到的差（即挠动脉脉搏波形中的搏动成份）加以放大和一定的相位补偿，并用它驱动电压／气压转换器 24 去控制气囊 3 进一步从外部对挠动脉 7 施加其波形与动脉内血压波形一样的压力。如图 8 中的闭环状态(为了清楚起见，闭环状态的各波形在时间轴上被展开)开始的部分所示，这将使得挠动脉脉搏振幅开始变小。显然，当伺服放大电路 37 的增益被调节到使气囊 3 加在挠动脉 7 外部的压力不仅在波形的形状上，而且在波形的幅值上也完全与挠动脉内部的血压波形相同，即使得挠动脉 7 血管壁的内外两侧的受力达到动态平衡时，如图 8 中的闭环状态后面的部分所示，挠动脉 7 的血管壁将不再随血管内血压的周期性变化而搏动，其血管容积将被完全嵌定在其无载状态容积 V 上。所以在闭环工作状态下，只要令系统在逐渐增加伺服放大电路 37 的增益的同时，找到挠动脉 7 的脉搏振幅最终趋于零的时间点，就可以肯定由此开始加压气囊 3 内的压力在任何时刻都与挠动脉 7 内的血压相等，这时用与加压气囊 3 相连的压力传感器 25 连续测量加压气囊 3 内的压力即可实现挠动脉血压波形的无创伤连续测量。

该实施例特别适用于需要长时间测量血压，并且血压变化急剧（例如麻醉、手术、急症）的病人的临床监护。

实施例 3

本发明的实施例 3 是一个对手腕桡动脉既可进行间断血压值测量、又可进行连续血压波形测量的方法和装置，如图 9 所示。本实施例的测量定位方法和最佳脉搏选择方法均与

实施例 1 相同。其主要区别在于将选出的最佳脉搏信号交替地用于容积振动法无创伤测量平均压和收缩压和用于容积补偿法无创伤连续测量挠动脉血压波形。

本实施例的装置也包括一个腕部探测装置和一个供压－测量系统。腕部探测装置以及供压－测量系统的大部分都与前面两个实施例中的相同，不同的是为了既可进行间断血压值测量、又可进行连续血压波形测量，如图 9 所示，须将第一个实施例中最佳脉搏信号选择电路以后的基于容积振动法的的供压－测量系统(即图 1 中用于控制读出气囊的压力值的部分 29, 30, 31)与第二个实施例中最佳脉搏信号选择电路以后的基于容积补偿法的供压－测量系统(即图 7 中用于控制气囊压力的变化的反馈控制系统 34, 35, 36, 37)通过一个“间断测量－连续测量”的功能选择开关 39 加以切换。由于这种切换是很简单的，在此不再赘述。

对于血压变化有时平缓、有时急剧的病人，采用本实施例可以根据病人的病情在从零到无限大的范围内自由地选择测量间隔在临床或家庭进行长时间的血压监护。

实施例 4

本发明的实施例 4 是在挠动脉 7 和尺动脉 9 两根动脉上交替地进行间断的或／和连续的血压测量。其测量定位方法和最佳脉搏选择方法与上述实施例相同，其主要的区别是在桡动脉 7 和尺动脉 9 上分别各压置一个设有脉搏传感器的加压囊体 3 和 3′，在两根动脉上交替地进行血压测量。

本实施例中，桡动脉加压囊体 3 内所设有脉搏传感器采用如上述实施例相同的传感器阵列 4。但在尺动脉加压囊体 3′内的脉搏传感器可以仅为相互并联的光电传感器，最好在尺动脉 9 加压囊体的加压范围内沿手腕的周向排列 2 个以上相互并联的光电传感器。

本实施例中，在对尺动脉 9 进行血压测量时，须利用桡动脉 7 血压测量结果作为标准对尺动脉血压测量结果进行校准。即求出测得的桡动脉 7 的平均压与测得的尺动脉 9 脉搏振幅最大点所对应的囊体压力的差 Di，同时求出测量尺动脉压的过程中，囊体 3 压力等于桡动脉 7 的收缩压时的尺动脉 9 脉搏振幅与其最大振幅的比例 Pi。这样，在后面再测量尺动脉血压时，每次将新测得的尺动脉 9 脉搏振幅最大点所对应的囊体压力减去 Di，得出这次的平均压；同时，在体囊压力低于这次的平均压的范围内找到尺动脉脉搏振幅中与其最大振幅成比例 Pi 的点所对应的囊体压力，得出这次的收缩压。

在利用桡动脉 7 血压测量结果对尺动脉 9 血压测量结果进行校准时，可将两个加压囊体 3 和 3′连通，利用容积振动法同时在桡动脉 7 和尺动脉 9 测量一次血压。

或者，在利用桡动脉 7 的血压测量结果对尺动脉 9 的血压测量结果进行校准时，也可以将桡动脉 7 血压测量和尺动脉 9 血压测量分开先后相继进行。

采用本实施例的方法进行长时间连续血压过程中，应自动定期地根据上述校准方法重新测定 Di 和 Pi;

为实现本实施例方法，本实施例所采用的装置也包括一个基本上与第一个实施例中的相同的腕部探测装置 0，只是如图 10 所示，在气囊绑带 5 上原有的桡动脉加压气囊 3 的对侧再设置一个用于对尺动脉加压的气囊 3′，其内部也设有一个脉搏传感器用于检测尺动脉脉搏。另外，它具有采用两个相互独立的上述的三个实施例当中的任何一种供压－测量装置，从而利用切换装置交替地对桡动脉和尺动脉进行间断的或连续的血压测量。

在本实施例中，桡动脉加压气囊以及其中的桡动脉脉搏传感器也都应采用与第一个实施例中相同的结构，以便同样准确地测量桡动脉血压；尺动脉加压气囊 3′可以采用与第一个实施例中相同的结构，但尺动脉脉搏传感器不一定要采用象桡动脉脉搏传感器那样复杂的光电传感器阵列．这是由于如图 3 所示，因为尺动脉 9 位置较深，且它与其上方的皮表之间存在着肌腱 11，使得气囊压力不易充分地传递到尺动脉 9，因此在手腕外部的任何位置都难以准确地测量出尺动脉的血压值。一般，在通常的气囊压力范围内，在尺动脉上可以检测出脉搏振幅的最大点，但检测不出消失点，而且其最大点对应的气囊压力总是高于动脉中的平均压。不过为了便于找到尺动脉，最好在尺动脉的大约位置上沿手腕的周向排列 2 个以上相互并联的光电传感器。显然，当采用相互并联的光电传感器时，用于尺动脉脉搏信号的放大·滤波电路也只需要 1 个通道，而且可以省略最佳脉搏选择电路。

由于对于同一个被测腕部而言，桡动脉血压和尺动脉血压基本上相同；并且如果被测腕部没有大的转动，尺动脉气囊 3′内的压力与实际传递到尺动脉 9 的压力的差也基本上是恒定的，所以在本实施例中，每次对尺动脉进行血压测量时，应利用桡动脉血压测量结果作为标准进行校准．校准时可将两个加压囊体 3 和 3′连通，利用容积振动法同时在桡动脉和尺动脉测量一次血压，然后求出测得的桡动脉的平均压与测得的尺动脉脉搏振幅最大点所对应的囊体压力的差 Di，同时求出测量尺动脉压的过程中，囊体压力等于桡动脉的收缩压时的尺动脉脉搏振幅与其最大振幅的比例 Pi。这样，在后面再测量尺动脉血压时，每次将新测得的尺动脉脉搏振幅最大点所对应的囊体压力减去 Di，得出这次的平均压；同时，在体囊压力低于这次的平均压的范围内找到尺动脉脉搏振幅中与其最大振幅成比例 Pi 的点所对应的囊体压力，得出这次的收缩压。为了防止由于被测腕部有过大的转动改变了 Di 和 Pi，在长时间连续测量血压过程中，应自动定期地用象测量开始时一样的方法重新测定 Di 和 Pi。

在本实施例中，为了简化电路，也可将对桡动脉和尺动脉进行血压测量的两个相互独立的供压－测量装置中的除了脉搏信号放大·滤波、最佳脉搏信号选择以及脉搏振幅检测部分以外的其它部分共用一个。当然也可将用于对桡动脉 7 和尺动脉 9 进行血压测量的供

压－测量装置可以完全共用一个供压－测量装置，而在对桡动脉 7 和尺动脉 9 中的某一根动脉进行血压测量时，通过一个切换装置将供压－测量装置交替地与被测动脉上的囊体管道以及脉搏信号输出端相连接。不过这样简化后，由于不能再在同一次血压测量同时获得分别两根动脉的血压测量值，故在利用桡动脉血压测量结果对尺动脉血压测量结果进行校准时，须将对桡动脉的血压测量与对尺动脉的血压测量分开先后相继进行。其校准方法与上述的类似，只是用于作为标准的桡动脉血压测量结果不是在尺动脉血压测量的同时测得的，而是与尺动脉血压测量相邻的一次血压测量的结果。

由于交替使用两根动脉可以避免长时间持续压迫一处所造成的疼痛和麻木，该方法可使频繁或连续测量血压的时间得以无限制地延长。

实施例 5

本实施例所采用的方法与上述实施例相同。

本实施例 5 的装置是把上述实施例中的供压－测量系统中的压力传感器、电压／气压转换器、甚至整个供压－测量系统与腕部探测装置做成一体。这样可以减少测量时的连线和管道，更便于临床应用；而且，对于对于利用容积补偿法连续测量血压来说，这样做还可以大大提高压力反馈控制的速度，从而进一步提高血压波形的测量精度。

实施例 6

本发明的实施例 6 是将上述的 5 个实施例所描述的任何一种无创伤手腕血压测量装置与其它生理参数（例如心电、呼吸、体温等）的测量记录装置做成一体，构成多参数生命体征监护仪。

实施例 7

本发明的实施例 7 是将上述的 6 个实施例所描述的任何一种无创伤手腕血压测量装置与数据记录装置（例如磁带记录仪、集成电路存贮器等）相连接或做成一体并小型化，构成便携式可外出用的长时间血压监测装置。

实施例 8

本发明的实施例 8 是将上述的 7 个实施例所描述的任何一种无创伤手腕血压测量装置与有线或无线通讯装置（例如无线电发射机、有线电话或无线电话等）相连接，构成可向医疗机构传送测量结果和获得医疗指导的远距离血压监控网络。

实施例 9

本实施例的测量定位方法、最佳脉搏选择方法以及测量方法与实施便 1 相同。但实施例 9 的装置是在实施例 1 的基础上进行的简化改进，在本实施例中，省略了其中的手腕固定托 6。为实现本发明的正确测量定位，测量时，被测者根据本装置的使用要求，自己保持手腕部 18 和手根部 17 不动，并使得手腕部 18 相对于前臂的转角和手根部相对于手腕部的夹角保持在上述的最适合测量桡动脉血压的角度上，然后按照最佳脉搏传感器位置显示正确地缠绕固定好气囊固定绑带，以此测量出桡动脉的平均压、收缩压以及舒张压。根据本实施例可以制成方便于家庭日常检查血压或观察高血压治疗效果、以及门诊进行体检用的简易型的手腕血压计。

上述实施例仅用于说明本发明，而非用于限定本发明。本发明还可以有多种实施和改进的方案。例如，在上述的四个实施例中，我们利用了间断测量动脉血压的容积振动法以及连续测量动脉血压的容积补偿法。其中都采用被测动脉得脉搏振幅是否达到最大作为判断被测动脉血管是否处于无载状态的判据，并采用控制气压来控制对被测动脉施加的外部压力，和采用光电传感器来检测动脉脉搏。实际上，可采用其它判据，例如脉搏波形的形状或基线高度的变化、在脉搏波形上人为叠加上去的小振动波的振幅的变化、血流速度的变化等，来判定被测动脉的无载状态；也可以采用控制液压来控制对被测动脉施加的外部压力和采用其它能够用于检测动脉脉搏的传感器来检测动脉脉搏。

00-04-21

说 明 书 附 图

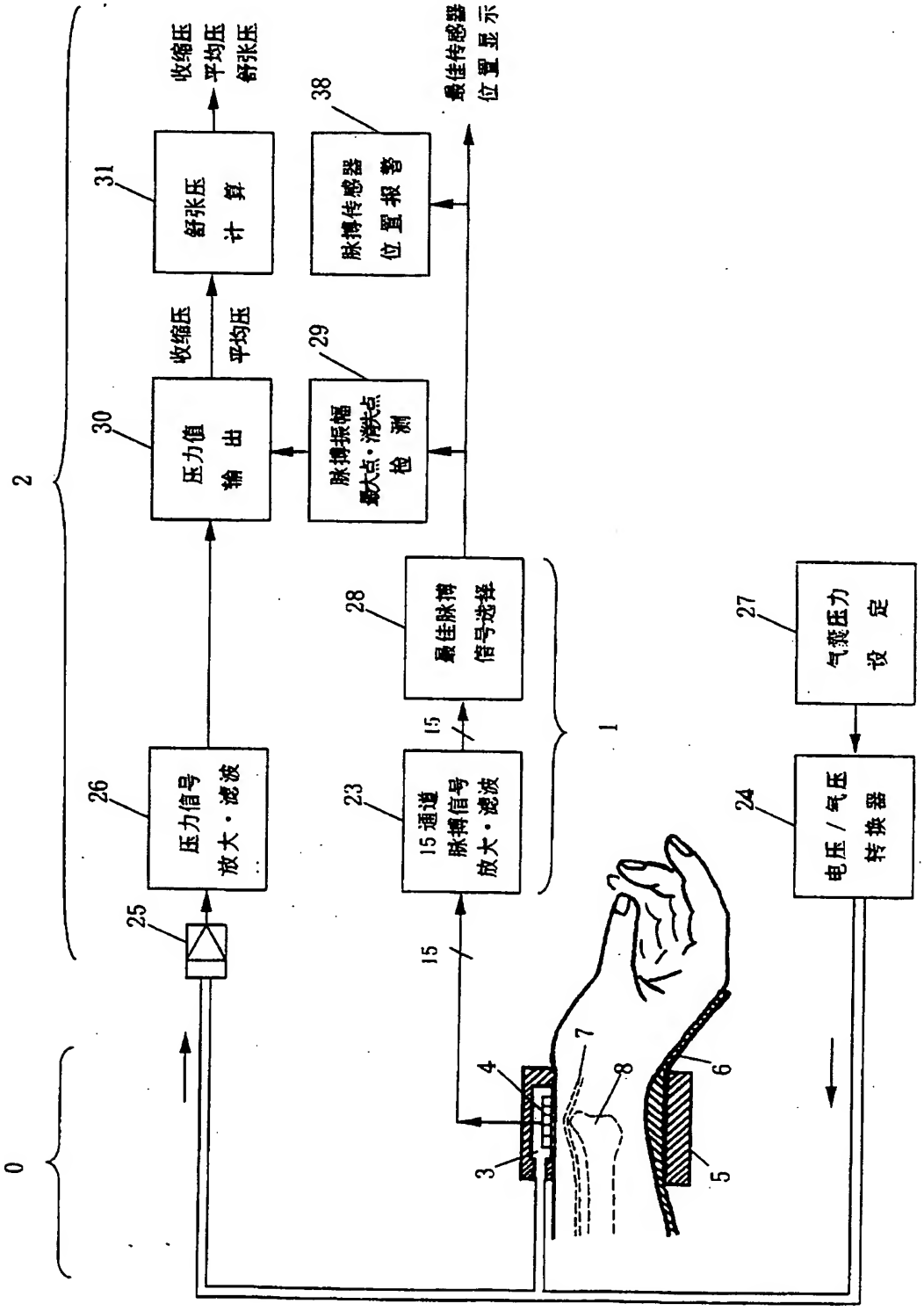

图 1

00-04-21

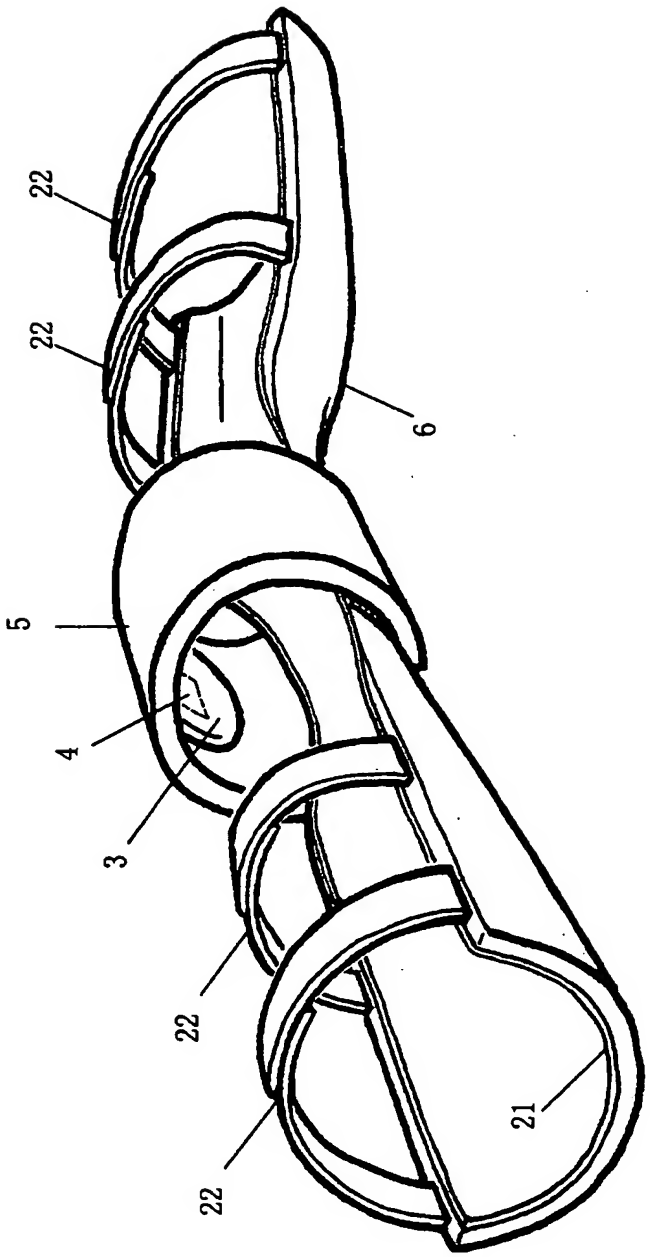

図2

00.04.21

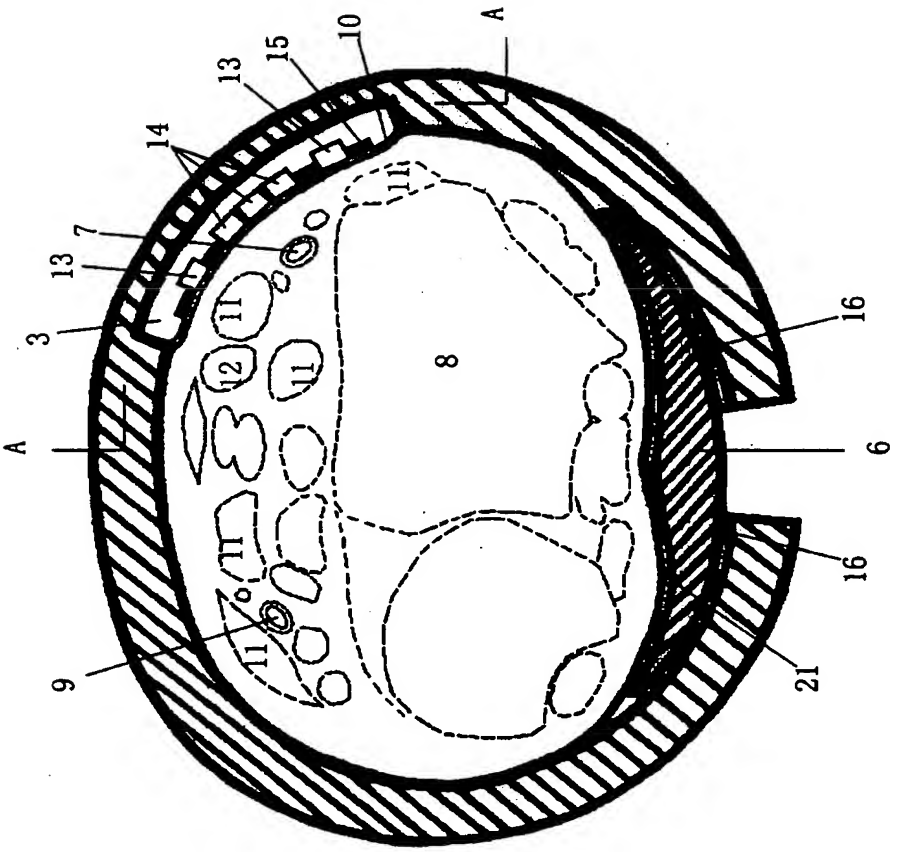

图3

00.04.21

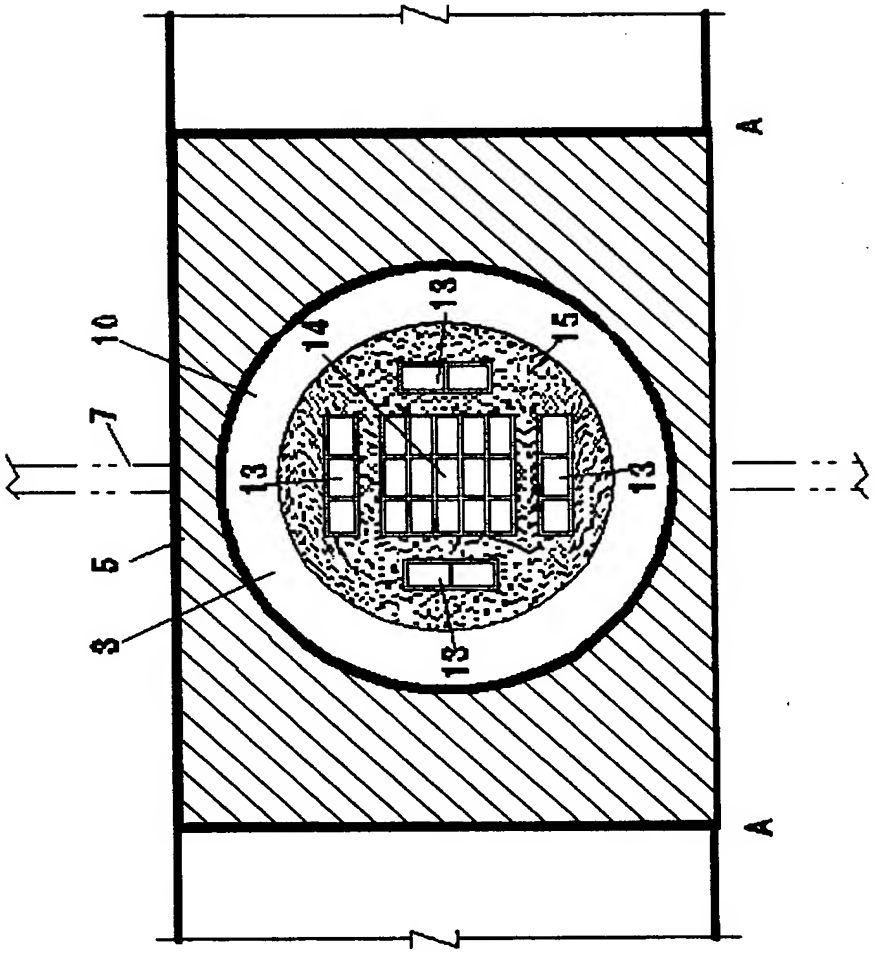

图 4

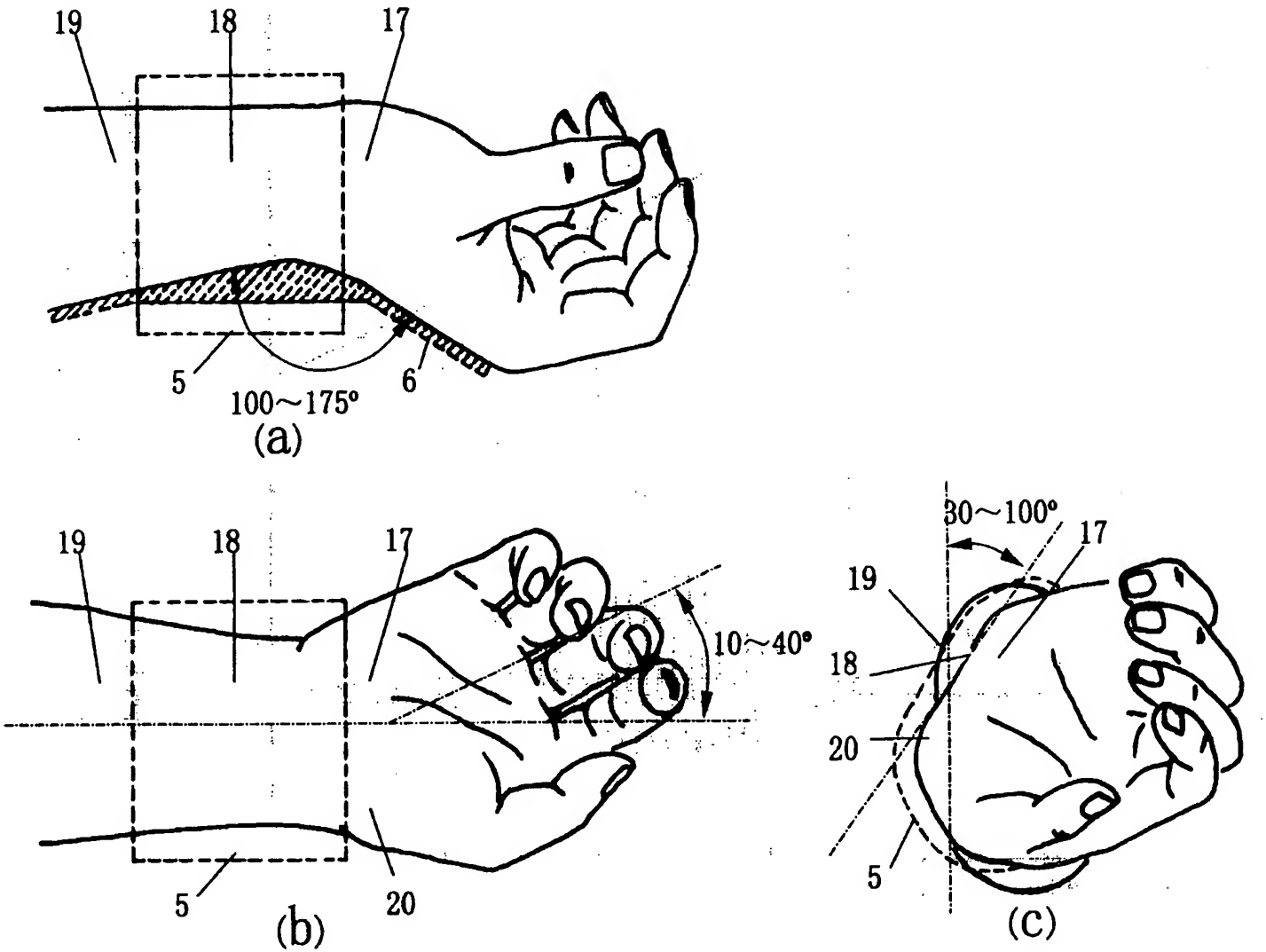

图 5

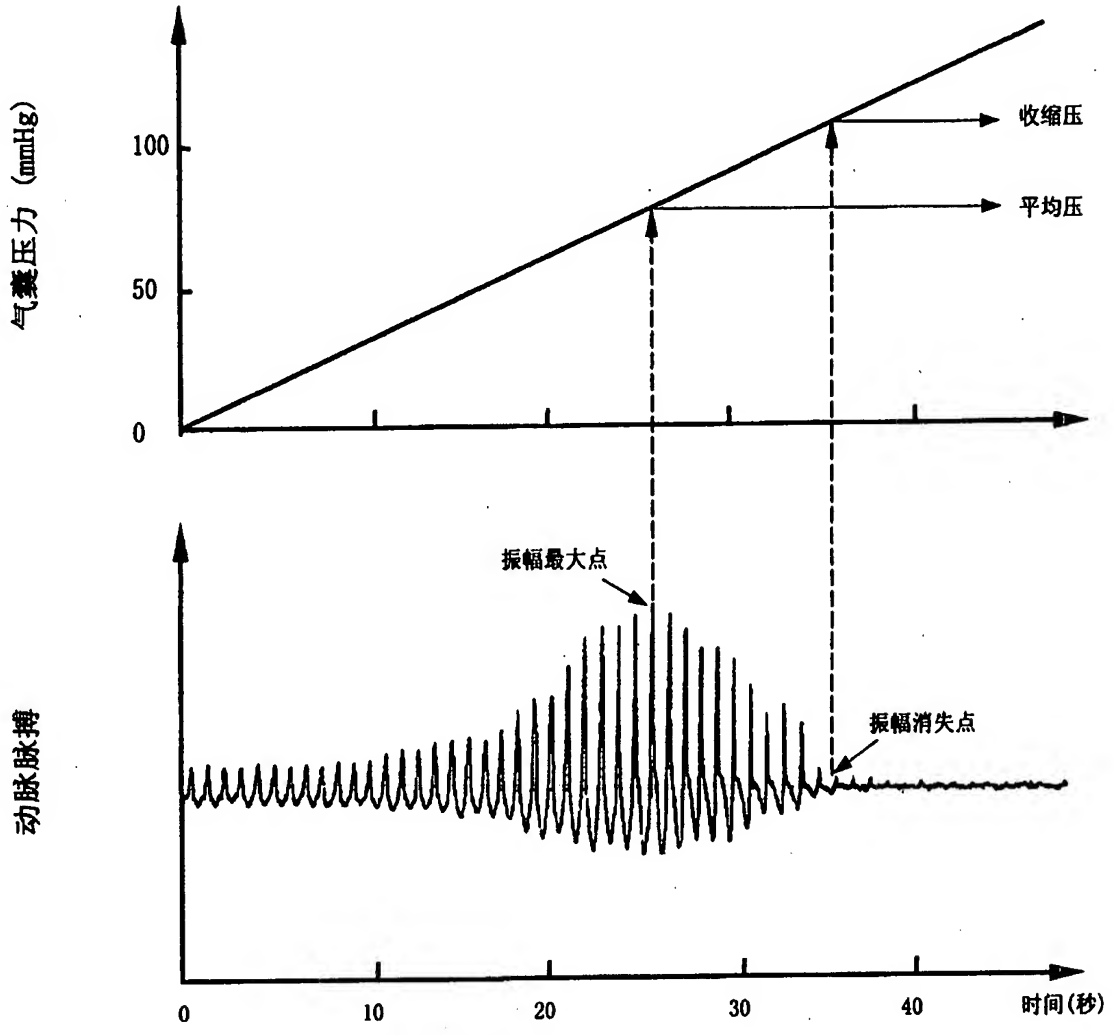

图 6

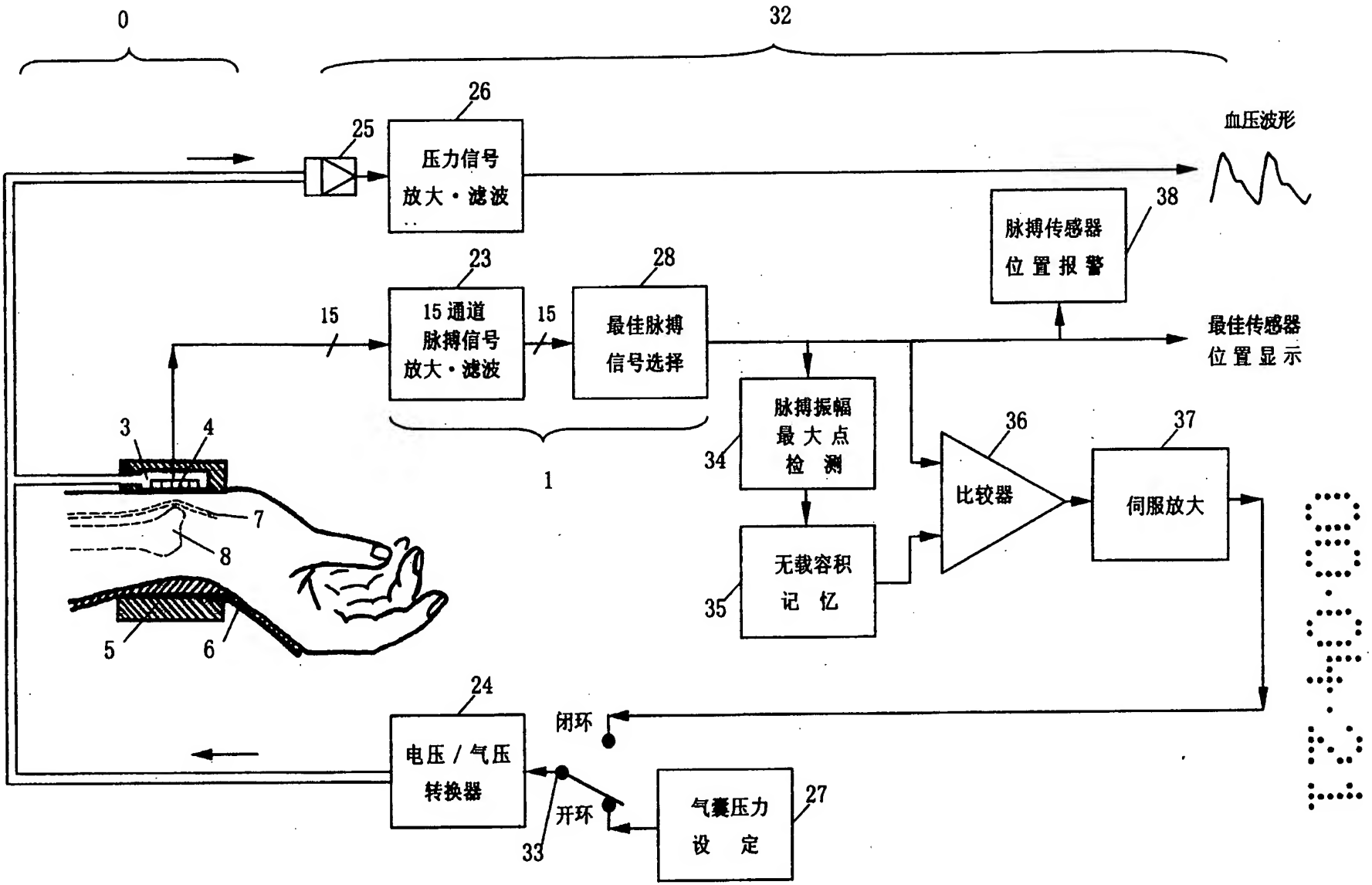
0
32
26
25
压力信号
放大·滤波
血压波形
脉搏传感器
位置报警
38
23
28
15
15通道
脉搏信号
放大·滤波
15
最佳脉搏
信号选择
最佳传感器
位置显示
脉搏振幅
最大点
检测
34
1
3
4
36
37
比较器
伺服放大
7
8
无载容积
记忆
35
5
6
24
闭环
电压/气压
转换器
开环
33
气囊压力
设定
27

图 7

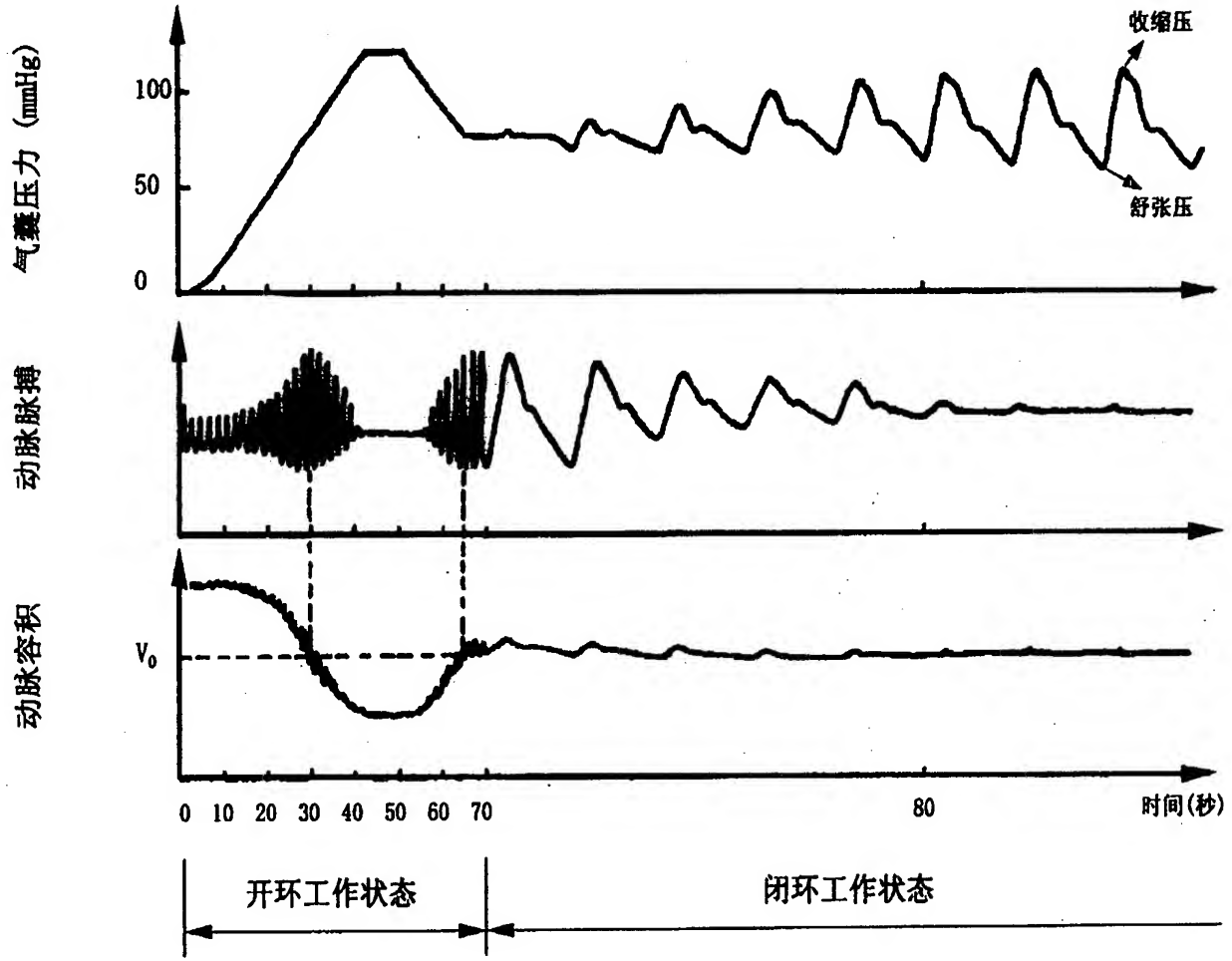
气囊压力（mmHg）
100
50
0
收缩压
舒张压
动脉脉搏
动脉容积
V_0
0 10 20 30 40 50 60 70
80
时间(秒)
开环工作状态
闭环工作状态

图 8

00.04.21

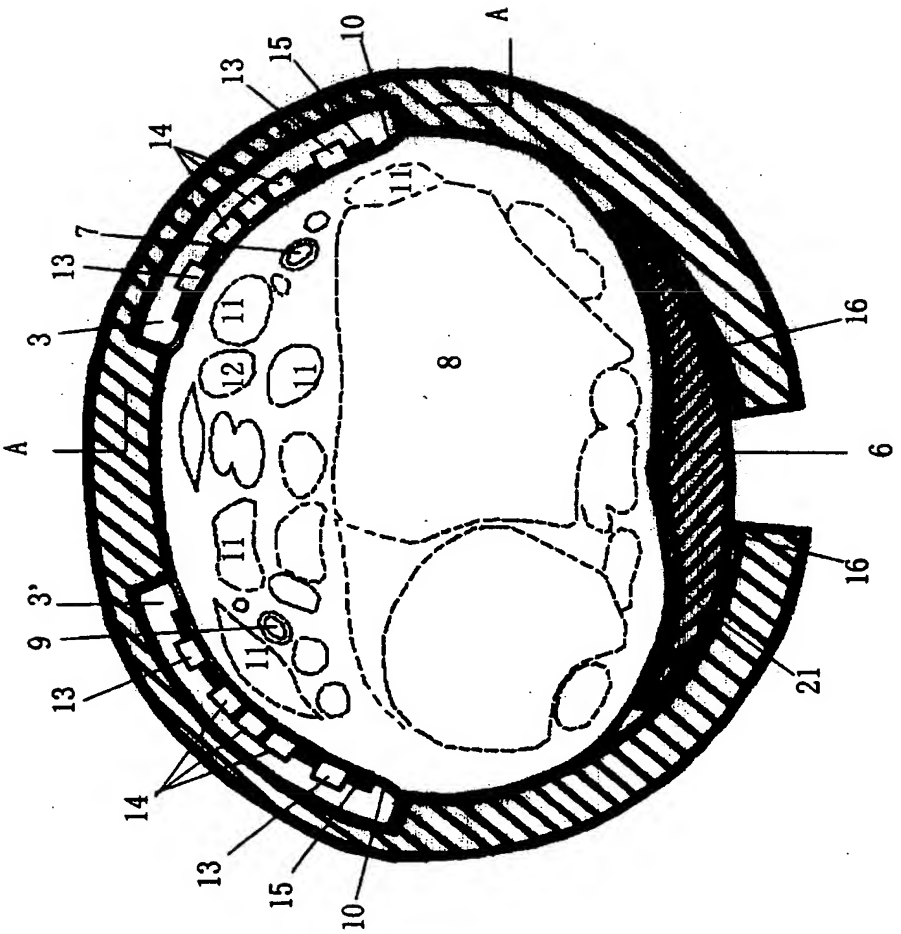

图9

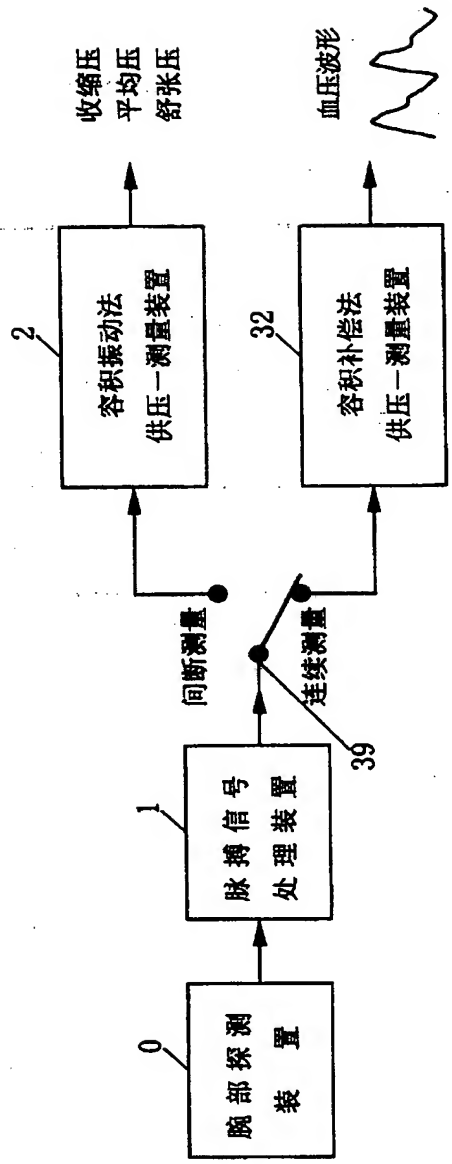
0
腕部探测装置
1
脉搏信号处理装置
39
间断测量
连续测量
2
容积振动法供压—测量装置
32
容积补偿法供压—测量装置
收缩压
平均压
舒张压
血压波形

图 10

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A61B 5/022

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[71] **Applicant(s):** Lu Weiming
Address: Ningxia Medical College, Yinchuan, Ningxia Hui Autonomous Region (750004)
[72] **Inventor(s):** Lu Weiming
[74] **Patent Agency:** BEIJING SANYOU INTELLECTUAL PROPERTY AGENCY CO., LTD.
Agent: Ma Yajia

6 pages of claims, 16 pages of specification, and 10 pages of figures inside

[54] **TITLE OF INVENTION:** A Method And a Device for Noninvasive Blood Pressure Measurement

[57] **ABSTRACT**

A method and a device for noninvasive continuous blood pressure measurement, wherein the angle between the lower part of palm and the wrist, and the turning angle of the wrist relative to the forearm, are both kept to the most applicable degree for measuring the blood pressure of the radial artery, with at least one pressure ballonet and one arterial pulse sensor array being placed on the skin over the radial artery of the wrist to apply external pressure to the artery and to detect the change of the arterial pulse signals. This method and device can easily and correctly measure the intermittent or continuous blood pressure of the radial artery or the ulnar artery based on volume oscillation method and volume compensation method, with no influence from the body movement. Also, it can eliminate the influence on blood circulation and neural function of the hand caused by long-term blood pressure measurement.

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Claims

1. A method of noninvasive blood pressure measurement, with at least one arterial pulse sensor array being placed on the skin over the radial artery of the wrist to detect arterial pulse signals, wherein

the said method at least keeps the angle between the lower part of palm and the wrist to the most applicable degree for measuring the blood pressure of the radial artery. It can lower the position of the tendons and cause the radial artery to be close to the radius.

2. The method of noninvasive blood pressure measurement in claim 1, wherein

it is preferred to keep the dorsal side of the wrist and the dorsal side of the lower part of palm at an angle of 100 - 175° during the measurement of blood pressure.

3. The method of noninvasive blood pressure measurement in claim 1, wherein

the said step keeps a turning angle of the wrist relative to the forearm to the most applicable degree for measuring the blood pressure of the radial artery. It makes the radial artery be closer to the radius.

4. The method of noninvasive blood pressure measurement in claim 3, wherein

it is preferred to keep the volar side of wrist relative to the volar side of the forearm (near elbow joint) at a turning angle of 30 - 100° towards the medial side of body during the measurement of blood pressure.

5. The method of noninvasive blood pressure measurement in claim 1, the method comprising the steps of:

A. At least place a pressure ballonet and an arterial pulse sensor array on the skin over the volar jut at the distal end of the wrist radius, and keep the positions of the sensor array and the ballonet relatively unchanged against the said jut;

B. Make control over the pressure of the ballonet, with a lower limit less than the expected average blood pressure of the examinee and an upper limit higher than the expected systolic blood pressure.

C. As the ballonet pressure increase/decrease, the pulse sensor array detects the pulse signals rounded up from the radial artery at different sites of the wrist, and then send it to an optimal pulse signal selecting circuit. The pulse amplitude is higher for those obtained from the sensor-point nearer to the radial artery; On the other hand, for the signals detected at a site with better transfer of pressure, the mean blood pressure and systolic blood pressure shown in the pulse signals can be lower. Therefore, selection of the most pressure-transfer-friendly sensor-point over the radial artery comprises the steps of: analyze the signals of the array row by row (with arrays in parallel with the radial artery) and select the sensor row which possesses the highest pulsation when the maximum amplitude is reached; to select the optimal point from all the points of the pre-selected row, choose the sensor point which has the maximum amplitude as the ballonet pressure runs up, but almost has the pulsation disappearing and be constant as the ballonet pressure runs up higher than the maximum pulsation, and the ballonet pressure corresponding to the maximum amplitude and the disappearing point of the pulse signal being the lowest among all the pre-selected points; the pulse signal detected at the optimal point is deemed as the optimal pulse signal.

D. Apply the optimal pulse signal to the noninvasive measurement of the radial artery blood pressure.

6. The method of noninvasive blood pressure measurement in claim 5, wherein

the pulse sensor array is preferably positioned at the center of the pressure area of the pressure ballonet. Thus, when the sensor detecting the optimal pulse signal is positioned at the center of the said sensor array, the central point of the pressure ballonet that has the most pressure power is accurately aligned with the most pressure-transfer-friendly point of the said sensor.

7. The method of noninvasive blood pressure measurement in claim 6, wherein
once the optimal pulse signal is selected, the position of the corresponding sensor in the sensor array is visually displayed, and the position of the ballonet is adjusted according to the display, so that the optimal sensor site is positioned at the center of the array.

8. The method of noninvasive blood pressure measurement in claim 7, wherein
when measuring the blood pressure for long time, an automatic check is carried out to see if the optimal sensor position is at the center of the array. Should the sensor shift away from the center of the array, an alarming signal would be given so as to prompt the operator to readjust the position of the pressure ballonet.

9. The method of noninvasive blood pressure measurement in claim 5, wherein
the arterial sensor array is preferably secured on the inner surface of the ballonet (facing the wrist), so as not to influence the even distribution of ballonet pressure over the wrist surface.

10. The method of noninvasive blood pressure measurement in claim 5, wherein
it is preferred to turn the lower part of palm towards the little finger during the radial artery blood pressure measurement, forming a deflecting angle of 10 - 40° from the central line of the lower part of palm relative to the central line of the volar side of the wrist, such that the palm bulge below the thumb does not hamper the close contact of ballonet holding strap to the wrist.

11. The method of noninvasive blood pressure measurement in claim 5, wherein
the diametric gap between the wrist-palm joint and the section near the forearm is filled up, and the irregular surface at the dorsal side of the wrist-palm joint caused by lower part of palm's bending backwards is smoothed up into a regular cylinder, thus preventing the slippage of the entire pressure ballonet along the long axis of the wrist toward the lower part of palm when inflated and boosting the stability of the ballonet;

12. The method of noninvasive blood pressure measurement in claim 5, wherein
the contact area between the securing means (for both the ballonet and the wrist) and the wrist is large enough, so as to decrease the pressure acting on the other parts of the wrist when the ballonet is being inflated;

13. The method of noninvasive blood pressure measurement in claim 5, wherein
the selected optimal pulse signal is used in volume oscillation method for the measurement of the mean and the systolic blood pressures against the selected optimal pulse signal.

14. The method of noninvasive blood pressure measurement in claim 5, wherein
the selected optimal pulse signal is used in volume compensation method for the measurement of the mean and the systolic blood pressures against the selected optimal pulse signal.

15. The method of noninvasive blood pressure measurement in claim 5, wherein
the selected optimal pulse signal is alternately used in volume oscillation method or volume compensation method for the measurement of the mean and the systolic blood pressures.

16. The method of noninvasive blood pressure measurement in claim 5, wherein
two sets of pressure ballonet and pulse sensor can be placed separately on radial artery and ulnar artery (one for each) to alternately measure the blood pressure.

17. The method of noninvasive blood pressure measurement in claim 16, wherein
the pulse sensors for ulnar artery can also be shunt-wound photoelectric sensors, and it is preferred to place at least three shunt-wound photoelectric sensors in a line vertical to ulnar artery within the pressing scope of ulnar pressure ballonet.

18. The method of noninvasive blood pressure measurement in claim 16, wherein
when measuring the blood pressure of ulnar artery, the result of the radial artery blood pressure can be used as a standard to calibrate the result of the ulnar blood pressure measurement.

19. The method of noninvasive blood pressure measurement in claim 16, wherein
when using the result of radial artery blood pressure measurement as a standard to calibrate the result of ulnar blood pressure measurement, the following steps are involved: calculate the difference (Di) between the mean blood pressure measured from radial artery and the ballonet pressure of ulnar artery corresponding to the maximum pulse amplitude of ulnar arterial pulse, and at the same time calculate the ratio (Pi) of the ulnar arterial pulse amplitude to the maximum amplitude of the ulnar arterial pulse when the ballonet pressure of ulnar artery is equal to the systolic blood pressure during the measurement; each time thereafter, the new mean blood pressure of ulnar artery can be obtained by subtracting Di from the ballonet pressure of ulnar artery corresponding to the maximum amplitude of the measured ulnar arterial pulse, while the new systolic blood pressure of ulnar artery can also be obtained by seeking the ballonet pressure corresponding to the point where the ratio of ulnar arterial pulse amplitude to its maximum amplitude is Pi, provided that the ballonet be lower than the new mean blood pressure.

20. The method of noninvasive blood pressure measurement in claim 19, wherein
when using the result of radial artery blood pressure measurement as a standard to calibrate the result of ulnar artery blood pressure measurement, the two pressure ballonets can be connected by tubing, and then use volume oscillation method to measure radial artery blood pressure and ulnar artery blood pressure at the same time.

21. The method of noninvasive blood pressure measurement in claim 19, wherein
when using the result of radial artery blood pressure measurement as a standard to calibrate the result of ulnar artery blood pressure measurement, blood pressure measurement on radial artery and ulnar artery are carried out in succession.

22. The method of noninvasive blood pressure measurement in claim 16, 18, or 19, wherein
Di and Pi value should be measured periodically for long-term continuous measurement of blood pressure.

23. The method of noninvasive blood pressure measurement in claim 5, wherein
other criterions, such as the shape of the pulse waveform or the change in the level of the base line, the change in the oscillation amplitude of the small vibration wave added artificially to the pulse wave, and the change in the speed of blood flow in the artery being measured, can be used to judge the unloading state of the examinee's artery. In addition, hydraulic pressure control can also be used to control the external pressure applied to the examinee's artery, and other types of sensor that can detect the artery pulse are applicable in this invention.

24. A on-wrist detecting device for noninvasive blood pressure measurement, comprising at least one pressure ballonet secured by a holding means on the skin of either radial or ulnar artery, wherein
at least one arterial pulse sensor array is set on the pressing area of the radial artery pressure ballonet.

25. The on-wrist detecting device for noninvasive blood pressure measurement in claim 24, wherein
the said ballonet preferably form a round shape of pressing area, and the diameter should be 1/3 - 3/5 of the wrist diameter; the wrist-touching bottom part of the ballonet is made of substantially resilient membrane, with an arching out toward the wrist; the lateral and air-exposing top parts of the ballonet wall are made of considerably rigid material.

26. The on-wrist detecting device for noninvasive blood pressure measurement in claim 24, wherein
the said pulse sensor in the pulse sensor array is preferably a reflective photoelectric sensor that consists of at least one light emitting component and at least one photoelectric component, and most preferably has several photoelectric components closely arranged into an array at the center and has light emitting components arranged to the circumference of the array; facets of the said photoelectric component other than the light-receiving skin-adjacent facet are covered by light-shielding material.

27. The on-wrist detecting device for noninvasive blood pressure measurement in claim 26, wherein the said photoelectric component array consists of at least 2 components vertical to the radial artery and at least 2 components parallel to the radial artery, and each said component makes an outputting channel of radial arterial pulse signal.

28. The on-wrist detecting device for noninvasive blood pressure measurement in claim 26, wherein the said pulse sensor array preferably sits internally on the skin-contacting wall of the pressure ballonet, and the light-receiving facet of the photoelectric component and the light emitting facet of the light emitting component faces the said skin-contacting wall of the pressure ballonet; the center of photoelectric component array points to the center of the said skin contacting wall.

29. The on-wrist detecting device for noninvasive blood pressure measurement in claim 28, wherein the membrane fabricating the wrist-touching wall of the said pressure ballonet is light permeable at least at the part correspondent to the said sensor array.

30. The on-wrist detecting device for noninvasive blood pressure measurement in claim 24, wherein the said ballonet holding means is preferably a strap; the strap is made of considerably rigid and substantially resilient material, and shaped into a ring, the diameter of which is similar to that of the wrist, with an opening at the dorsal side of the wrist; the two ends of the opening should be connected by non-extensible means.

31. The on-wrist detecting device for noninvasive blood pressure measurement in claim 30, wherein the width of the said strap is preferably larger than diameter of the wrist, and the wrist-touching surface of strap fits well with the irregular surface of the wrist.

32. The on-wrist detecting device for noninvasive blood pressure measurement in claim 30, wherein the said ballonet holding strap is integrated into a whole with ballonet by: providing a strap of certain thickness, then on the facet of the strap that's toward the wrist, making an oblate pit which is in the same diameter as of the ballonet and in a location corresponding to the ballonet; adhering airtight the edge of the inner ballonet wall that is made of substantially resilient membrane to the margin of the strap pit that's toward the wrist.

33. The on-wrist detecting device for noninvasive blood pressure measurement in claim 24, wherein the said holding means is preferably supplied with a wrist-holding bracket; the said bracket is a curved board made of material with high rigidity, whose length and width covers at least the dorsal side of the hand, the dorsal side of the wrist, and the dorsal side of the forearm close to the elbow joint; its shape should keep an angle of 100 - 175° between the dorsal side of the wrist and the dorsal side of the lower part of palm, and synchronously keep the wrist relative to the forearm an a turning angle of 30 - 100° towards the medial side of body; also, it's preferably to form a deflecting angle of 10 - 40° towards the little finger from the central line of the lower part of palm relative to the central line of the volar side of the wrist.

34. The on-wrist detecting device for noninvasive blood pressure measurement in claim 33, wherein the said wrist-holding bracket has bolstered thickness at the connecting part of the dorsal side of the wrist and the dorsal side of the lower part of palm, so that the diametric gap between the wrist-palm joint and the section near the forearm is filled up, and the irregular surface at the dorsal side of the wrist-palm joint caused by lower part of palm's bending backwards is smoothed up into a regular cylinder.

35. The on-wrist detecting device for noninvasive blood pressure measurement in claim 33, wherein the said wrist-holding bracket has an internal surface fitting in with the irregularity of the dorsal side of the wrist.

36. The on-wrist detecting device for noninvasive blood pressure measurement in claim 33, wherein the said wrist-holding bracket is supplied with holding means for fastening both arm and hand.

37. The on-wrist detecting device for noninvasive blood pressure measurement in claim 24, wherein
the said pressure ballonet and artery pulse sensor can be placed on the skin over both radial artery and ulnar artery, and the pressing and the pulse detecting action for pressure ballonet and artery pulse sensor on either radial or ulnar artery can be alternately implemented through switching means.

38. The on-wrist detecting device for noninvasive blood pressure measurement in claim 37, wherein
the said pulse sensors for ulnar artery are preferably at least three adjacent photoelectric components in a line vertical to ulnar artery, and the said photoelectric components are shunt-wound and output a channel of ulnar artery pulse signal.

39. The on-wrist detecting device for noninvasive blood pressure measurement in claim 24, wherein
when measuring the blood pressure with the said on-wrist device, the pressure sensor connected to the pressure ballonet is combined with the ballonet holding strap into a whole.

40. A pulse signal processing device applying the on-wrist detecting device for noninvasive blood pressure measurement in any one of claim 24 - 39, wherein
the said device comprises at least one on-wrist detecting device, and the said on-wrist detecting device comprises at least one radial arterial pulse sensor array; a plurality of the radial arterial pulse signals is outputted from the said pulse sensor array, processed with amplification and filter, and eventually passed on to the optimal pulse signal selecting device.

41. The pulse signal processing device for noninvasive blood pressure measurement in claim 40, wherein
the said optimal pulse signal selecting device will analyze the signals of the pulse sensor array row by row (with arrays in parallel with the radial artery) and select the sensor row which possesses the highest pulsation when the maximum amplitude is reached; to select the optimal point from all the points of the pre-selected row, select the sensor point which has the maximum amplitude as the ballonet pressure runs up, but almost has the pulsation disappearing and be constant as the ballonet pressure runs up higher than the maximum pulsation, and the ballonet pressure corresponding to the maximum amplitude and the disappearing point of the pulse signal being the lowest among all the pre-selected points; the pulse signal detected at the optimal point is deemed as the optimal pulse signal.

42. The pulse signal processing device for noninvasive blood pressure measurement in claim 40 or 41, wherein
once the said optimal pulse signal is selected, an optimal pulse signal position display device is under control so that the specific position of pulse sensor array corresponding to the optimal pulse signal is visually displayed.

43. The pulse signal processing device for noninvasive blood pressure measurement in claim 40 or 41, wherein
a pulse sensor position alarming device is set such that an alarming signal would be given should the pulse sensor detecting the optimal pulse signal shift away from the center of the pulse sensor array.

44. The pulse signal processing device for noninvasive blood pressure measurement in claim 40, wherein
the said optimal pulse signal selecting device, the said optimal pulse signal position display device, and the said pulse sensor position alarming device can be combined with on-wrist detecting device into a whole.

45. A noninvasive blood pressure measurement device applying the said pulse signal processing device in any one of claim 40 - 44, wherein
the said device comprises at least one on-wrist detecting device defined above, and the on-wrist detecting device comprises at least one radial artery pressure ballonet and one radial artery pulse sensor array; the said pulse sensor array outputs a plurality of the radial arterial pulse signals, which are selected by the optimal pulse signal selecting device until a channel of optimal pulse signal is obtained. The said radial arterial pressure ballonet is connected to the pressure output of the voltage/pressure converter of the pressure supplying and measuring system and the pressure input of the pressure sensor, while the optimal radial artery pulse signal that the optimal pulse signal selecting device outputs is connected to the signal input of the pulse amplitude detecting device of the pressure supplying and measuring system.

46. The noninvasive blood pressure measurement device in claim 45, wherein
the said pressure supplying and measuring system can be used for intermittently measuring the mean blood pressure, systolic blood pressure and diastolic blood pressure of radial artery based on volume oscillation method.

47. The noninvasive blood pressure measurement device in claim 45, wherein
the said pressure supplying and measuring system can be used for continuously measuring the blood pressure waveform of the radial artery based on volume compensation method.

48. The noninvasive blood pressure measurement device in claim 45, wherein
a switching device can be used for the said pressure supplying and measuring system to intermittently measure the mean blood pressure, systolic blood pressure and diastolic blood pressure of radial artery based on volume oscillation method, or to continuously measure the instantaneous blood pressure of the radial artery based on volume compensation method.

49. The noninvasive blood pressure measurement device in any one of claim 45 - 48, wherein
the said on-wrist detecting device comprises two separate pressure ballonets, two separate arterial pulse sensors, and two separate pressure supplying and measuring systems, with a switching device to alternate between the intermittent or continuous measurement of blood pressure on either radial or ulnar artery.

50. The noninvasive blood pressure measurement device in claim 49, wherein
the said ulnar artery pulse sensor comprises several shunt-wound photoelectric components, and a channel of ulnar artery pulse signal output by them is amplified, filtered, and then directly passed on to the signal input of the pulse amplitude detecting device of the pressure supplying and measuring system for ulnar artery blood pressure.

51. The noninvasive blood pressure measurement device in claim 49, wherein
most parts of the said two separate pressure supplying and measuring systems can be shared in both blood pressure measurement of radial artery and blood pressure measurement of ulnar artery, except for those used for pulse signal amplifying, wave filtering, optimal pulse signal selecting and pulse amplitude detecting.

52. The noninvasive blood pressure measurement device in any one of claim 49- 51, wherein
one pressure supplying and measuring systems can be completely shared in both blood pressure measurement of radial artery and blood pressure measurement of ulnar artery; when measuring the blood pressure for either radial artery or ulnar artery, a switching device is used to alternatively connect the above pressure supplying and measuring systems to the pressure ballonet tubing of the corresponding artery and the signal output.

53. The noninvasive blood pressure measurement device in claim 49 or 50, wherein
it is preferred to set a calibrating device for calibrating the results of ulnar arterial blood pressure measurement with the results of radial arterial blood pressure measurement.

54. The noninvasive blood pressure measurement device in claim 49, wherein
the said optimal pulse selecting device, the optimal pulse signal position display device, the sensor position alarming device, and the pressure supplying and measuring system can be combined with the on-wrist detecting device into a whole.

55. The noninvasive blood pressure measurement device in claim 49 or 54, wherein
the said blood pressure measurement device can be combined with the blood pressure recording device into a whole.

56. The noninvasive blood pressure measurement device in claim 49 or 54 or 55, wherein
the said blood pressure measurement device can be combined with other physiological parameter detecting or recording devices into a whole.

57. Any one of the noninvasive blood pressure measurement device in claim 49 or 54-56, wherein
the said blood pressure measurement device can be connected to the communicating apparatus.

Specification

TITLE: A METHOD AND A DEVICE FOR NONINVASIVE BLOOD PRESSURE MEASUREMENT

This invention relates to a method and a device for noninvasive measurement of blood pressure, and in particular relates to a method and the corresponding device for intermittent measurement of arterial blood pressure on the basis of so-called volume oscillation method, as well as a method and the corresponding device for continuous measurement of arterial blood pressure on the basis of volume compensation method.

The volume oscillation method (also called volume oscillometric method) is based on the principle that the blood vessel will have the highest flexibility (this state is called the "unloading state") when the extra-vascular pressure is equal to the mean blood pressure, and will be flattened when the extra-vascular pressure is higher than the intra-vascular systolic blood pressure. Since the intra-vascular blood pressure is periodically changing along with the heart beat all the time (during a heart-beating cycle, the highest pressure is called systolic blood pressure, the lowest pressure is called diastolic blood pressure, and the average of all pressure values over a heartbeat cycle is called the mean blood pressure), and in accord with the variation of blood pressure the diameter (or volume) of the artery is changing periodically and forming the arterial pulse, the pulsation will be at its maximum when the vascular wall has the most flexibility at the point the extra-vascular blood pressure equals the mean blood pressure; On the other hand, the pulsation will move down away when the blood vessel is flattened as a result of that the extra-vascular blood pressure runs higher than the systolic blood pressure. When measuring the blood pressure with volume oscillation method, at first, an air ballonet (or liquid ballonet) is secured on the skin outside of the artery to apply external pressure to the artery, and as well a photoelectric sensor is applied for measuring arterial pulsation. Secondly, the ballonet pressure which is set within a range between a lower limit less than mean blood pressure value and an upper limit more than systolic blood pressure value is enabled to make a linear or gradual increase/decrease by a rate of 3 mmHg/sec. The variation of pulsation amplitude is measured during the term of ballonet pressure change. If the ballonet pressure can be transmitted accurately downward the central area of the ballonet through the soft tissues to the outer of the blood vessel and the pulse sensor will only detect the arterial pulse from these soft tissues, the ballonet pressure corresponding to the maximum amplitude and to the disappearing point of the amplitude will equal mean blood pressure and systolic blood pressure respectively. Therefore, the mean blood pressure and the systolic blood pressure can be measured with a pressure sensor to show the ballonet pressures at the above two points. Furthermore, the diastolic blood pressure can be obtained by figuring out an estimation algorithm (Diastolic Blood Pressure = (3 * Mean Blood Pressure – Systolic Blood Pressure) /2). This method can only measure blood pressure intermittently because each process of pressure increase/decrease for one cycle of measurement of the blood pressure needs a considerable amount of time. Compared to the traditional ways for noninvasive intermittent blood pressure measurements such as stethoscopy, palpation, rubefaction and supersonic, volume oscillation method is capable of obtaining mean blood pressure and eliminating subjectivity induced measuring errors; in addition, it is simple in structure and easy to operate. Furthermore, the volume oscillation method is advantageously able to make an accurate measurement on systolic blood pressure value instead of doing a statistical deduction as current clinic and family-popular means of pressure oscillation method (also called oscillometric method) do.

Volume compensation method (also called vascular unloading method) is based on the principle that the diameter of the blood vessel will not change with the wave of the blood pressure in the vessel (or will not pulsate), but will maintain at its unloading state when the pressure outside the vessel is equal to the internal blood pressure at any given time. This method includes an air ballonet (or liquid ballonet) that applies the external pressure to the artery and a photoelectric sensor to detect the arterial pulse, plus a feedback control system that uses the measured arterial pulse to control the pressure of the ballonet. When measuring the blood pressure continuously by using volume compensation method, at first, like the volume oscillation method, change the ballonet pressure in a certain range, and at the same time measure the change of pulse amplitude as the ballonet pressure change. When the ballonet pressure is equal to the mean intra-arterial pressure (that is, the vascular wall is the most flexible, and the amplitude of the pulse is the highest), the feedback control system is on and then performs magnification and phase compensation on the detected pulse waves. The pulse waves will be further used to control the ballonet pressure so that it will change accordingly with the pulse wave on the basis of the mean pressure. Once the extra-vascular pressure changes in the same pattern as the intra-vascular pressure does, both in shape and in amplitude (that is, the extra-vascular and intra-vascular forces find a dynamic balance), the diameter of the artery vessel does not change along with the waving of the intra-vascular pressure, but remains at an unloading state (that is, the pulse oscillation amplitude is near to zero). If a pressure sensor continuously measures the ballonet pressure now, the continuous measurement of the instantaneous blood pressure and its waves can be obtained at the same time. Characterized by its noninvasiveness, this method is easy to operate and does not cause pain, bleeding, infection, thrombosis, and other nervous injuries and related complications and sequelae that are otherwise commonly seen in traditional continuous blood pressure measuring means by using direct intra-arterial cannulation. Furthermore, compared to tension method (also called counterforce method) introduced in recent years, it has such advantages as no need to calibrate the results obtained from volume compensation method and measure results hardly subject to disturbance of body movement.

The two methods mentioned above are not used on the upper arm where the blood pressure is normally measured for now, but on the finger to measure the blood pressure of the finger artery. This is mainly because the position of the brachial artery for the upper arm is very deep, so that external pressure must be applied to the upper arm all-round or almost all-round the arm to supply adequate external pressure to the brachial artery. Because of the excessive pressure, frequent use of the volume oscillation method for intermittent blood pressure measurement, or long-term use of the volume oscillation method for continuous blood pressure measurement will seriously affect the forearm and the entire hand in blood circulation and neural function. However, the position of the finger artery is shallow. It's convenient to implement photoelectric pulse detection. When measuring the finger blood pressure, the influence on the blood circulation and neural function of the finger, caused by the increased ballonet pressure, is less. Numerous clinical results have shown that the two above mentioned blood pressure measurement methods have another big problem if they are carried out on fingers, that is, because the finger artery is a part of distal arteriolar 'web', compared with the so-called "systemic blood pressure" (or the blood pressure of the aorta near the heart) that is clinically used for judging whether the patient's blood pressure is normal or not, blood pressure of finger is around 10 mmHg lower under normal conditions. In case of arteriosclerosis, the gap can reach dozens of mmHg. More importantly, because there are more smooth muscles in the small artery vessel wall than in the aortal wall, the vessels are very easily intrigued by various factors (such as coldness, anesthesia, etc.) to produce either vasoconstriction or vasodilation. As a result, the blood pressure in the small artery fluctuates in a great range, and the blood pressure shown at finger artery cannot reflect the systemic blood pressure of the patient under many circumstances. In rare cases, the patient's functional circulation is very weak, so the finger artery can be somehow lacking in blood flow due to the extreme vasoconstriction. At this time the blood pressure cannot be measured at the finger.

In order to match the correct systemic blood pressure and not to affect the blood circulation of the distal ends involved in the measurement, it was recently proposed to apply the two methods on a substitute measuring site-the wrist and also modify the traditional all-round pressure ballonet to a lateral pressure ballonet pressing on only one of the two arteries (radial or ulnar) at the wrist. It is based on two points: 1) Radial or ulnar artery is much bigger in diameter than the finger artery, and the amount of smooth muscles in the vessel wall is less than that in the finger artery. As a result, the blood pressure there reaches closer to the systemic blood pressure than on the finger artery, and becomes more resistant to surrounding influences. In addition, even if the patient's functional circulation is very weak, the pulse can be normally detected from the radial artery or ulnar artery, making the measurement of the blood pressure possible. In particular, whereas the said features and the maneuverability of measuring on wrist arteries, the direct invasive blood pressure measurement, which has been deemed as a standardized commonsense tool in operating theatres and ICU all over the world, is making clinical staff get used to the blood pressure value read on the wrist being the most accurate and reliable blood pressure indication. So it is expected that even if it is obtained by substituting noninvasive methods for invasive ones, the clinical prevalence will come as long as it is from the wrist. 2) Normally, there are over two 'bigger' arteries and two 'bigger' veins on the wrist, of which two arteries (radial artery and ulnar artery) crisscross each other twice at two arches in the palm; and several veins meet in a vein 'web' at the back of hand. Due to the connection of these blood vessels, it is accepted that even if one artery and/or partial vein is blocked for long time, the other artery and most of the veins will still have blood fluency, thus the whole circulation of the hand will not be substantially affected. Therefore, it is possible to conduct frequent and continuous blood pressure measurement by applying the two methods on either radial or ulnar artery.

Although related studies have shown that the mean blood pressure, systolic blood pressure, and the blood pressure wave can be separately and accurately measured by applying volume oscillation method and volume compensation method to the radial artery at the volar jut of the distal end of the radius, studies have also discovered that actually it is very difficult to measure accurate blood pressure on the wrist. This is mainly owing to the sensitivity of the blood pressure measurement precision to the position of photoelectric sensor. Even at a site very close to the volar jut of the distal end of the radius, different points will induce a great difference among the blood pressure values for a distance of only 2 mm or 3mm. In addition, the precision of the measurement is also affected by some external factors, for example, 1) the measured blood pressure will vary greatly when the wrist spins around the forearm axis or when the hand bends forwards or backward; 2) as the ballonet pressure increase, the ballonet might move forward or backward to the fingers, and/or move along or around the wrist. All these movements may change the inflation of the ballonet, and the movement around the wrist and along the long axis may also cause the photoelectric sensor to be displaced. The displacement of the photoelectric sensor will affect the measuring precision of volume oscillation method and volume compensation method, while the change of ballonet inflation may make the volume compensation method imprecise and even destroy the stability of feedback control system. In addition, the looseness of ballonet that may be often seen in long-term measurement may also affect the precision of volume compensation method and the stability of the feedback control system. On the other hand, these studies also reveal that the holding strap of ballonet could apply a considerable pressure to the wrist such that the downstream circulation and neural function might be greatly affected after a long-term blood pressure measurement task. In particular, long-term continuous ballonet pressure might cause pain of the pressed area.

The goal of the invention is to provide a method and a device which can apply the principles of the volume oscillation method and the volume compensation method to the measurement of intermittent or continuous blood pressure at the radial and/or the ulnar artery in a simple and accurate way and without obvious influences resulted from external factors, while also effectively eliminating the impact against the blood circulation and neural function of the hand from long-term continuous measurement.

To reach the said goal, the solution the current invention provides is as follows:

1. At least, the angle between the wrist and the lower part of palm is kept to the most applicable degree for measuring the blood pressure of the radial artery. In addition, it is preferred to keep the turning angle of the wrist relative to the forearm to the most applicable degree for measuring the radial arterial blood pressure. The two angles are optimally united to ensure that tendons and nerves beside the radial artery are depressed so that the artery is raised nearest to the radius and possibly pressed by the pressure ballonet in an effective way. When measuring the blood pressure repeatedly or continuously for a long time, in order to guarantee the said angle is right for on-wrist measurement, this invention also uses a wrist-holding bracket to maintain the turning of the wrist and the bending of the lower part of palm, so that relative to the radial artery the positions of the pressure ballonet and the pulse sensor, as well as the tendon, nerves, and radius inside of the wrist, stay the same during the measurement however the patient moves.

2. For the purpose of locating an optimal site where the most accurate measurement can be conducted for the blood pressure of the radial artery, it is preferred to set a pulse sensor array on the center of the pressure area of the pressure ballonet that is placed on the skin over the radial artery of the wrist at the volar jut of the distal end of the radius. As the ballonet pressure increase/decrease, the pulse sensor array detects the pulse signals rounded up from the radial artery at different sites of the wrist, and then send it to a pulse signal optimization circuit. The pulse amplitude is higher for those obtained from the sensor-point nearer to the radial artery; On the other hand, for the signals detected at a site with better transfer of pressure, the mean blood pressure and systolic blood pressure shown in the pulse signals can be lower. Therefore, selection of the most pressure-transfer-friendly sensor-point over the radial artery comprises the steps of: analyze the signals of the array row by row (with arrays in parallel with the radial artery) and select the sensor row which possesses the highest pulsation when the maximum amplitude is reached; to select the optimal point from all the points of the pre-selected row, select the sensor point which has the maximum amplitude as the ballonet pressure runs up, but almost has the pulsation disappearing and be constant as the ballonet pressure runs up higher than the maximum pulsation, and the ballonet pressure corresponding to the maximum amplitude and the disappearing point of the pulse signal being the lowest among all the pre-selected points; the pulse signal detected at the optimal point is deemed as the optimal pulse signal. The optimal pulse signal to the noninvasive measurement of the radial artery blood pressure will be used in volume oscillation method or volume compensation method for radial arterial blood pressure measurement. To align the pressure ballonet center that has the most pressure power with the selected position that can precisely detect the radial arterial blood pressure, the position of the sensor in the sensor array that detects the optimal pulse signal is displayed in the most visual way, and then adjust the position of the ballonet according to the display so that the sensor detecting the optimal pulse signal is positioned at the center of the sensor array. When measuring the blood pressure for long time, to prevent the body movement of the examinee causing the shift of the measuring location, an automatic check is carried out to see if the optimal sensor position is at the center of the array. Should the sensor shift away from the center of the array, an alarming signal would be given so as to prompt the operator to readjust the position of the pressure ballonet.

3. It is preferred to turn the lower part of palm towards the little finger to a small degree, so as to keep the palm bulges away from the volar jut at the radial end and not hamper the close contact of the holding strap with this wrist section when a large ballonet is applied.

4. To prevent the slippage of the entire pressure ballonet along the long axis of the wrist toward the lower part of palm when inflated and boost the stability of the ballonet strap, the diametric gap between the wrist-palm joint and the section near the forearm should be filled up. Also, the irregular surface at the dorsal side of the wrist-palm joint caused by lower part of palm's bending backwards should be smoothed up into a regular cylinder

5. In order to decrease the pressure acting on the other parts of the wrist when the ballonet is being inflated, it is preferred to have the securing means (for both the ballonet and the wrist) bearing a large enough contact area with the wrist.

6. In order to reduce the pain and numbness caused by long-term continuous pressure applied on the specific site, it is preferred to place two pressure ballonets separately on the radial and ulnar artery (one for each), so that the blood pressure can be measured alternately. As it is difficult to make accurate blood pressure measurement on the ulnar artery, the result of the radial artery blood pressure can be used as a standard to calibrate the result of the ulnar blood pressure measurement. That is, calculate the difference (Di) between the mean blood pressure measured from the radial artery (synchronously or in succession) and the ballonet pressure of ulnar artery corresponding to the maximum pulse amplitude of ulnar arterial pulse, and at the same time calculate the ratio (Pi) of the ulnar arterial pulse amplitude to the maximum amplitude of the ulnar arterial pulse when the ballonet pressure of ulnar artery is equal to the systolic blood pressure during the measurement; each time thereafter, the new mean blood pressure of ulnar artery can be obtained by subtracting Di from the ballonet pressure of ulnar artery corresponding to the maximum amplitude of the measured ulnar arterial pulse, while the new systolic blood pressure of ulnar artery can also be obtained by seeking the ballonet pressure corresponding to the point where the ratio of ulnar arterial pulse amplitude to its maximum amplitude is Pi, provided that the ballonet be lower than the new mean blood pressure. It is possible that the Di and Pi be changed due to the overmuch movement of examinee's wrist. So, Di and Pi value should be measured periodically for long-term measurement of blood pressure.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1: the general flow chart of the first embodiment of this invention;

FIG. 2: the perspective view for the on-wrist detecting device of the first embodiment as shown in FIG. 1;

FIG. 3: the cross-section for the on-wrist detecting device as shown in FIG. 2, with the section plane vertical to the wrist and central to the external pressure ballonet of the on-wrist detecting device;

FIG. 4: the cross-section for the A-A section of the on-wrist detecting device as shown in FIG. 3, reflecting the arrangement of the arterial pulse sensor in the pressure ballonet;

FIG. 5: the schematic illustration for the three angles between the wrist and the lower part of palm, formed by the wrist-holding bracket of the on-wrist detecting device as shown in FIG. 2;

FIG. 6: the schematic illustration for the measurement method of the mean blood pressure and systolic blood pressure of the first embodiment as shown in FIG. 1;

FIG. 7: the general flow chart of the second embodiment of this invention;

FIG. 8: the schematic illustration for the measurement method of the blood pressure waveform of the second embodiment;

FIG. 9: the general flow chart for the third embodiment of this invention;

FIG. 10: the cross-section for the on-wrist detecting device in the fourth embodiment of this invention, with the section plane vertical to the wrist and central to the external pressure ballonet of the on-wrist detecting device.

EMBODIMENTS OF THE INVENTION:

Embodiment 1

The first embodiment of this invention is a method for noninvasive intermittent measurement of the blood pressure on the wrist with the volume oscillation method.

First of all, the positioning method of this embodiment is shown in FIG 5. The angle between the wrist (18) and the lower part of palm (17) is kept to the most applicable degree for measuring the blood pressure of the radial artery, preferably at 100 - 175°; In addition, keep the turning angle of the wrist (18) relative to the forearm (19) to the most applicable degree for measuring the radial arterial blood pressure, preferably at 30 - 100°. The two angles are optimally united to ensure that tendons and nerves beside the radial artery are depressed so that the artery is raised nearest to the radius and possible pressed by the pressure ballonet in an effective way.

When measuring the blood pressure repeatedly or continuously for a long time, in order to guarantee the said angles are right for the on-wrist measurement, as shown in FIG 2, this invention can also use a wrist-holding bracket (6) to maintain the turning of the wrist (18) and the bending of the lower part of palm (17), so that relative to the radial artery the positions of the pressure ballonet (5) and the pulse sensor array, as well as the tendon, nerves, and radius inside of the wrist, stay the same during the measurement.

After being positioned as above, the method of noninvasive blood pressure measurement of this embodiment, as shown in FIG. 1 and FIG. 6, comprises the steps of:

A. At least set a pressure ballonet (3) and an arterial pulse sensor array (4) over the skin on the volar jut of the distal end of the wrist radius (7), and keep the position of the sensor array and the ballonet relatively unchanged to this site;

B. Make control over the pressure of the ballonet (3), with a lower limit less than the expected average blood pressure of the examinee and an upper limit higher than the expected systolic blood pressure. When the pressure of the ballonet (3) is changing, no distorts except for the surface of the ballonet (3) adjacent to the wrist should occur too (without circumferential tension), and no displacement should occur.

C. As the ballonet (3) pressure increase/decrease, the pulse sensor array (4) detects the pulse signals rounded up from the radial artery at different sites of the wrist, and then send it to a pulse signal optimization circuit (28). The pulse amplitude is higher for those obtained from the sensor-point nearer to the radial artery; On the other hand, for the signals detected at a site with better transfer of pressure, the mean blood pressure and systolic blood pressure shown in the pulse signals can be lower. Therefore, selection of the most pressure-transfer-friendly sensor-point over the radial artery (7) comprises the steps of: analyze the signals of the array row by row (with arrays in parallel with the radial artery) and select the sensor row which possesses the highest pulsation when the maximum amplitude is reached; to select the optimal point from all the points of the pre-selected row, choose the sensor point which has the maximum amplitude as the ballonet pressure runs up, but almost has the pulsation disappearing and be constant as the ballonet pressure runs up higher than the maximum pulsation (FIG. 6), and the ballonet pressure corresponding to the maximum amplitude and the disappearing point of the pulse signal being the lowest among all the pre-selected points; the pulse signal detected at the optimal point is deemed as the optimal pulse signal.

D. Applying the selected optimal pulse signal to the noninvasive measurement of the radial artery blood pressure. In this embodiment, the optimal pulse signal is applied to the noninvasive measurement of the mean blood pressure and the systolic blood pressure with the volume oscillation method.

In this embodiment, the arterial pulse sensor array (4) is preferably positioned at the center of the pressure area of the pressure ballonet (3). Thus, when the sensor detecting the optimal pulse signal at the optimal pressure-transfer site is positioned at the center of the said sensor array (4), the central point of the pressure area of the pressure ballonet (3) that has the most pressure power is accurately aligned with the most pressure-transfer-friendly point.

Once the optimal pulse signal is selected, the position of the corresponding sensor in the sensor array is visually displayed, and the position of the ballonet (3) is adjusted according to the display, so that the optimal site is positioned at the center of the array (4), and the central point of the pressure area of the pressure ballonet (3) that has the most pressure power is at the most pressure-transfer-friendly point.

When this embodiment is applied to a long-term blood pressure measurement, an automatic check is carried out to see if the optimal sensor position is at the center of the array (4). Should the sensor shift away from the center of the array, an alarming signal would be given so as to prompt the operator to readjust the position of the pressure ballonet (3).

In this embodiment, the arterial pulse sensor array (4) is secured on the inner surface of the ballonet (facing the wrist), so as to be able to get the pulse signal directly from artery (7) while not influence the even distribution of ballonet pressure over the wrist surface.

While measuring the arterial blood pressure, it is preferred to turn the lower part of palm (17) toward the little finger forming a deflecting angle of 10 - 40° from the central line of the lower part of palm relative to the central line of the volar side of the wrist (18), such that the palm bulge (20) below the thumb does not hamper the close contact of ballonet (3) holding strap to the wrist (FIG. 5b).

To prevent the slippage of the entire pressure ballonet (3) along the long axis of the wrist toward the lower part of palm when inflated and boost the stability of the ballonet strap, the diametric gap between the wrist (18) - palm (17) joint and the section near the forearm (19) is filled up in this embodiment. Also, the irregular surface at the dorsal side of the wrist-palm joint caused by lower part of palm (17)'s bending backwards is smoothed up into a regular cylinder.

In order to decrease the pressure acting on the other parts of the wrist (18) when the ballonet (3) is being inflated, it is preferred to have the securing means (for both the securing means (5) of ballonet (3) and the securing means (6) of the wrist) bearing a large enough contact area with the wrist.

As shown in FIG.1, the device based on the said method in this embodiment comprises three parts: Part I is a on-wrist detecting device (0) for applying external pressure and detecting the pulse of radial artery (7); Part II is a pulse signal processing device (1) for selecting the optimal pulse signal transferred from on-wrist detecting device (0); Part III is a pressure supplying and measuring system (2) to feed pressure to ballonet (3) and measure both the ballonet pressure and the radial arterial pulsation for the purpose of measuring the radial arterial blood pressure.

Part I, the on-wrist detecting device (0), is described as follows. As shown in FIG. 2 and FIG. 3, in this embodiment, the measurement of blood pressure of the radial artery (7) is realized when the external pressure to the radial artery is applied and the radial arterial pulse in wrist is detected. The on-wrist detecting device (0) comprises the following four parts: the pressure ballonet (3), the arterial pulse sensor (4), the ballonet holding strap (5), and the wrist-holding bracket (6).

As shown in FIG. 2 and FIG. 3, the radial artery pressure ballonet (3) of this embodiment is an oblate ballonet. In order to ensure that the ballonet pressure can sufficiently reach the depth of the radial artery (7), ballonet (3) should be positioned until its center is aligned with the radial artery (7) on the volar jut of the distal end of the radius (8); On the other hand, the diameter of the ballonet (3) should be large enough, although excessively large diameter will press the ulnar artery (9) and other veins. So, this diameter can be 1/3 - 3/5 of the wrist diameter (e.g. 30 mm or so for adult). In addition, in order for ballonet (3) not to produce circumferential tension on the inner surface but to press the radial artery (7) effectively, the inner surface (10) of the ballonet (3) (wrist-touching) is made of transparent, resilient membrane (10), with an arching out toward the wrist; the lateral and air-exposing top parts of the ballonet (3) wall are made of considerably rigid material.

The radial arterial pulse sensor (4) is an array of reflective photoelectric sensors. There are complicated heterogeneous structures inside the wrist, as shown in FIG. 3. In the surroundings of the radial artery (7), there is radius (8) beneath it, as well as supporting-tissue-based tendons (11) and nerves (12) by both sides. These tendons and nerves may have substantially high rigidity and hamper the pressure transmission. In accordance with the mechanical principle, it is hypothesized that the ideal site for transferring the ballonet pressure effectively to the radial artery (7) and for measuring the blood pressure of the radial artery (7) accurately is the point nearest to the skin and the radius (8), but furthest from the tendons (11) and nerves (12). However, in a real wrist (see FIG. 1, FIG. 3), the depth and position of the radial artery (7) itself, as well as the shape and position of the tendons (11) and radius (8), is varying as the direction of the wrist axis changes. Especially, the volar jut of the distal end of the radius (8) is irregular in cross-section view and different from person to person. Obviously, for the purpose of locating an ideal point for accurate radial arterial blood pressure measurement, it is necessary to use sensors array (4) to make multi-site detections followed by analysis and comparison. In order to fix the sensors (4) together with the pressure ballonet (3) onto the wrist, and not to influence the even distribution of ballonet pressure (10) over the wrist surface, sensor array 4 is mounted inside the ballonet (3). As shown in FIG. 4, in this embodiment, the sensor array 4 consists of ten infrared light emitting diodes (13) and fifteen phototransistors (14), among which the fifteen phototransistors (14) form a rectangle array. This array has three rows of phototransistors in parallel of the radial artery (7), and each row consists of five phototransistors. There is space between either the columns or the rows. The ten infrared light emitting diodes (13) are arranged around the rectangular array, with good clearance. These emitting diodes (13) and phototransistors (14) are secured on the inner surface of the semi-transparent membrane- fabricated inner wall (10) of the said ballonet (3). When fixing, the light emitting surface of the emitting diodes (13) and the light receiving surface of the phototransistors (14) should face the inside of the inner membrane wall (10), and the center of the phototransistor array should aim to the center of the inner membrane wall (10). In addition, in order to ensure the phototransistors (14) not to absorb the light from both the light emitting diodes (13) and the environment, a layer of shading sheet (15) with good extensibility (for instance, black sponge sheet) is glued between the light emitting diodes (13) and the phototransistor array, as well as on the circumference of the whole phototransistor array. When detecting the pulse of the radial artery (7) with this phototransistor, the infrared light is emitted by the ten light-emitting diodes (13) from ten different sites, passing the inner semi-transparent membrane wall (10) into the wrist. As the blood pressure changes periodically, radial artery (7) changes its volume, and this make the light reflection in the phototransistors (14) alter its intensity accordingly. As a result, the output current of the phototransistors (14) varies. In such a way, the fifteen phototransistors (14) will transfer the volumetric changes of radial artery (7) at fifteen points separately into fifteen channels of electric signal output.

Ballonet holding strap (5) is used to fix the pressure ballonet (3) with the pulse sensor (4) inside to the wrist above. In fact, to simplify the structure, this embodiment integrates the ballonet (3) and the holding strap (5) into one on-wrist detecting device. This is done by steps of: use a strap of certain thickness and rigidity to make an oblate pit which is diametrically the same as the ballonet (3) at the site facing the wrist (corresponding to ballonet); adhere the edge of the inner ballonet wall (10) made of membrane to the margin of the pit of strap (5) towards the wrist. The inner wall (10) made of membrane is integrated with the considerably rigid pit of the strap (5) into the said ballonet (3). In order for the outer wall of the ballonet not to move towards the finger ends during ballonet inflation, the strap (5) should be made from substantially non-extensible material, so it is with the buckle-up accessories. In this embodiment, the two ends of the strap (5) are secured to the wrist-holding bracket (6) through nylon buckle (16). Meanwhile, to prevent the circumferential movement of ballonet (3) during the ballonet inflation, the strap (5) should be considerably rigid in full length (at least between the dorsal side of the radius (8) and the volar side of the ulnar, if the ballonet is seen as center). This circumferential movement of the ballonet is owing to the elliptical shape of wrist in cross-section view, while the ballonet (3) applying pressure to radial artery (7) is a partially pressed one, which is placed exactly on the connection of the two different arcs. The tension in ballonet-inflation-induced strap (5) will certainly create an imbalance between the two sides of the ballonet, so as to cause the circumferential movement of the ballonet (3). The movement again causes the shape change of the strap (5), so good rigidity could resist such movement. In addition, the strap (5) should possess appreciable elasticity so that when the diameter of the wrist is reduced due to long-term, continuous pressure, its resilient capability can still enable the ballonet (3) to wrap tightly onto the wrist without any movement. On the other hand, in order to ensure the radial artery (7) is sufficiently pressured by the ballonet (3) only, and to decrease the pressure of strap (5) acting on the other parts of the wrist at most, it is preferred to have the strap (5) bearing an enough large contacting area with the wrist. So the strap (5) should be as wide as possible (preferably more than 50 mm for adults), and fit well in with the irregularity of the wrist (18) and the lower part of the palm (17).

The wrist-holding bracket (6) is a curved board made of highly rigid material. Its length and width should cover the entire dorsal side of the hand, the entire dorsal side of the wrist and the entire dorsal side of the forearm. The wrist-holding bracket (6) has three functions. The first function is to keep the angle between the wrist (18) and the lower part of palm (17) and the angle between the wrist (18) and the forearm (19) to the most applicable posture for measuring the blood pressure of the radial artery. At the same time, it limits the turning of the wrist (18) and the bending of the lower part of palm (17) such that relative to the radial artery (7), the position of the pressure ballonet (3) and the pulse sensor (4), as well as the tendon (11), nerves (12), and radius (8) inside the wrist stays the same during the movement. As shown in FIG. 5(a) and FIG. 5(c), the shape of the wrist-holding bracket (6) should make the angle between the dorsal side of the wrist (18) and the dorsal side of the hand (17) be 100 - 175°, and make the turning angle of the wrist (18) relative to the forearm (19) be 30 - 100° towards the medial side of body. The two angles are optimally united to ensure that tendons (11) and nerves (12) beside the radial artery (7) are depressed so that the artery (7) is raised nearest to the radius (8) and possible to be pressed by the pressure ballonet (3) in an effective way. Furthermore, the holding bracket also makes the deflecting angle of the central line of the hand (17) relative to the central line of the volar side of the wrist (18) be at 10 - 40° towards the little finger, as shown in FIG 5b. In such, the hand bulge (20) below the thumb can move away from the volar jut of the radial distal end, so that the holding strap (5) for big ballonet can closely hold the wrist. The second function of the wrist-holding bracket (6) is to improve the ballonet holding stability of the strap (5). Considering that the entire ballonet (3) may slip axially along the wrist (18) towards the lower part of palm (17) by a partial force produced during the ballonet inflation in that the middle part of the forearm (19) is diametrically bigger than the wrist joint (17), a gradual increase of thickness is carried out on some parts of the bracket (6) corresponding to the connecting section between the dorsal side of hand (17) and the dorsal side of the wrist (18), so as to eliminate the gap of diameters between wrist joint (18) and the section near to the forearm (19). In addition, this increase can also boost the strength for holding the lower part of palm (17). Moreover, regarding that the wrist (18)-palm (17) joint will have an irregular surface at the dorsal side when it is bent backward, a make-up on the device is done again to obtain a regular cylinder shape. The third function of the wrist-holding bracket (6) is to disperse the pressure of the ballonet holding strap (5) on the dorsal side of the wrist.

For this reason, the inside of the wrist-holding bracket (6) should be shaped to match well with the irregular shape of the dorsal side of the wrist (18) (and it is preferred to get several kinds of bracket ready for different shapes and widths of the wrist). Also, in order not to discomfort the examinee with the excessively rigid bracket (6), a soft thin-layer cushion (21) could be adhered to the inner side of the bracket (6). In addition, several small laces (22) with nylon buckle endings are fastened onto the wrist-holding bracket (6) to keep the examinee's lower part of palm (17), the wrist (18), and the forearm (19) secured onto the wrist-holding bracket.

The principle of the device for noninvasive intermittent measurement of the radial artery blood pressure in this embodiment is:

As shown in FIG. 1, the fifteen outputs of the pulse sensor array (4) of the on-wrist detecting device (0) are connected individually with the fifteen inputs of the multi-channels of amplifier and filter (23) of the pulse signal processing device (1). At the same time, the tubing of the radial arterial pressure ballonet (3) is connected to the pressure output of the voltage/pressure converter (24) of the pressure supplying and measuring system (2) and the pressure input of the pressure sensor (25), which is connected to the pressure signal amplifier (26).

When setting up the on-wrist detecting device, the lower part of palm (17), the wrist (18) and the forearm (19) of the examinee are secured with the wrist-holding bracket (6) of the on-wrist detecting device (0). The center of the ballonet (3) of the on-wrist detecting device (0) is positioned directly to the radial artery (7) sitting on the volar jut of the distal end of the radius, and the ballonet holding strap (4) is enwound around the wrist (18). Lastly, the holding strap is secured to the wrist-holding bracket (6) by buckling up nylon buckles (16) at its two ends.

At the beginning of the blood pressure measurement, the ballonet pressure setting circuit (27) in the pressure supplying and measuring system (2) starts to adjust the input voltage of the voltage/pressure converter (24) automatically, so that the ballonet (3) in the on-wrist detecting device (0) is inflated to apply external pressure to the radial artery (7). Meanwhile, the pulse sensor array (4) of the on-wrist detecting device (0) measures the radial arterial pulse signals gathered from 15 sites, feeds them to the pulse signal processing device (1) for amplification and filter, and eventually passes them onto the optimal pulse signal selecting circuit (28). Due to the varying position, the pulse signals rounded up from the radial artery at the fifteen sites have different amplitude and shape of the envelop, and some of them may not have maximum point and disappearing point. Obviously, the pulse amplitude is larger if it is obtained from the sensor-point nearer to the radial artery; On the other hand, if detected at a site with better transfer of pressure, the mean blood pressure and systolic blood pressure shown in pulse signals can reach lower, therefore better for the accurate blood pressure measurement. So, selection of the most pressure-transfer-friendly sensor-point comprises the steps of: analyze the signals of the array row by row (with arrays in parallel with the radial artery) and select the sensor row which possesses the highest pulsation when the maximum amplitude is reached; to select the optimal point from all the points of the pre-selected row, choose the sensor point which has the maximum amplitude as the ballonet pressure runs up, but almost has the pulsation disappearing and be constant as the ballonet pressure runs up higher than the maximum pulsation, and the ballonet pressure corresponding to the maximum amplitude and the disappearing point of the pulse signal being the lowest among all the pre-selected points; the pulse signal detected at the optimal point is deemed as the optimal pulse signal.

The selected optimal pulse signal is fed to a circuit (29) for detecting pulse amplitude maximum point and the disappearance point. According to the principles of the volume oscillation method (FIG. 6), the ballonet pressures corresponding to the maximum point and the disappearance point equal the mean blood pressure and the systolic blood pressure of the artery respectively. Therefore, when the maximum point and the disappearance point are found by the amplitude detecting circuit (29), a control signal is given so that the ballonet pressure at the said two points are outputted by the pressure output circuit (30); thus, the mean blood pressure and the systolic pressure are obtained. Then, the diastolic blood pressure can be calculated through the diastolic blood pressure formula (31): (Diastolic Blood Pressure = (3 * Mean Blood Pressure – Systolic Blood Pressure) /2).

On the other hand, for the convenience of positioning, the selected optimal pulse signal is also used to display the best sensor location. The display can visually indicate the exact position of the sensor that owns the optimal pulse signal in the sensor array (e.g., give a drawing of the sensor array). When setting up the ballonet (3), the position of the ballonet (3) is adjusted according to the display, so that the sensor detecting the optimal pulse signal is positioned at the center of the sensor array. In this embodiment, there is also a pulse sensor position alarming circuit (38). When setting up the ballonet or during long-term measurement of the blood pressure, if the examinee's wrist turns violently (even though the wrist-holding bracket (6) can constrict the turning of the wrist (18) relative to the forearm (19), the wrist can still turn to a certain extent) such that the sensor is too far away from the center of the sensor array, the sensor position alarming circuit (38) will give alarming signal to prompt the operator to readjust the position of the pressure ballonet (3). Since the optimal pulse signal is selected for each run of the measurement, it is assured that the measurement is carried out at the optimal site for each time.

This embodiment is especially suitable for long-term clinic or family monitoring of blood pressure for the patient when his/her blood pressure has comparably mild changes (for example, after surgery or when recovering from treatment).

Embodiment 2

The second embodiment of this invention is a method and a device for noninvasive continuous measurement of radial artery blood pressure on the wrist based on volume compensation method. As shown in FIG. 7, the wrist positioning method and the measuring method in this embodiment is the same as that in the first embodiment. The main difference is that the selected optimal pulse signal is used in volume compensation method for noninvasive continuous measurement of the radial artery blood pressure waveform. As volume compensation method is a known technology, its operating process will be described in details hereinafter.

The device for this embodiment is shown in FIG. 7. The on-wrist detecting device (0) and pulse signal processing device (1) can be the same as in the first embodiment. The wrist-holding bracket and ballonet holding strap is also the same as in the first embodiment, so the description is not repeated herein. In this embodiment, the main difference from the first embodiment is that the output of the optimal pulse signal selecting circuit (28) of the pressure supplying and measuring system (32) is not used to control the pressure output circuit (30) to read the pressure of the ballonet (3), but is connected to the input of the voltage/pressure converter (24) to form a close-loop feedback control system and control the pressure change of the ballonet (3).

Before continuously measuring the blood pressure with this method and device, the pressure supplying and measuring system (32) turns the working state switch (33) to the "open-loop" state for the purpose of searching and recording the volumetric value of the radial artery (7) at its unloading state. As shown in FIG. 8, under the open-loop working state, like volume oscillation method, the ballonet pressure setting circuit (27) automatically adjusts the voltage fed to the voltage/pressure converter (24), so that the ballonet (3) in the on-wrist detecting device (0) will exert external pressure on radial artery (7). At the same time, the pulse signals of the radial artery (7) are detected by the pulse sensor array (4) in the on-wrist detecting device (0) from fifteen sites, and then fed to the optimal pulse signal selecting circuit (28) after amplification and filter. The selected optimal pulse signal is fed to the maximum amplitude detecting circuit (34). When the amplitude maximum point is found, that is, the radial artery (7) is pulsating in accord with the periodical change of the arterial blood pressure in an unloading state, the system has the ballonet pressure setting circuit (27) stop adjusting the pressure of the ballonet (3), and enable the unloading volume memorizing circuit (35) to memorize the average of the radial artery pulse waveform (D.C. component of the pulse signal) as the unloading volume (Vo) of examinee's radial artery.

Then, the pressure supplying and measuring system (32) automatically turns the working state switch (33) to the "close-loop" state. A comparing circuit (36) comes out to make a subtraction of the unloading-volume-based pulse signal which is detected by the pulse sensor from the unloading volume (Vo) memorized by the unloading volume memorizing circuit (35), and the servo amplifier (37) increases its gain gradually at the same time. Next, the subtracted difference (i.e. the pulsation in the radial artery pulse waveform) is amplified and phase compensated, and fed to the voltage/pressure converter (24) to control the pressure of ballonet (3) to further exert external pressure on radial artery (7) that have the same waveform as that of the arterial blood pressure. As a result, the amplitude of the radial arterial pulse is reduced, as shown in the beginning section of the close-loop state in FIG. 8 (to view easily, the waves in the close-loop state are extended along the time axis). Obviously, when the gain of the servo amplifier (37) is adjusted until the ballonet pressure on the radial artery (7) is completely the same as the blood pressure waveform of the radial artery in both shape and amplitude, i.e. when the force on either side of the wall of the radial artery (7) reaches a dynamic balance, as shown in the ending section of the close-loop state in FIG. 8, the wall of the radial artery (7) will not pulsate upon the periodical change of the blood pressure, and the blood vessel volume will maintain the unloading volume (Vo). Therefore, under the close-loop working state, as the gain of the servo amplifier (37) gradually increases, the system will reach a point that the pulse amplitude of the radial artery (7) becomes close to zero. After this point, the pressure in the pressure ballonet (3) will equal the blood pressure of the radial artery (7) at any time. Thus, the noninvasive continuous measurement of the radial artery blood pressure waveform is realized by continuously measuring the pressure of the pressure ballonet (3) with a pressure sensor (25) that is connected to the pressure ballonet (3).

This embodiment is especially suitable for the continuous clinical monitoring of patients that have sharp blood pressure changes (for example, patients under anesthesia, surgery, or intensive care).

Embodiment 3

This embodiment is a method and a device for both intermittent and continuous measurement of the blood pressure waveform on the radial artery of wrist, as shown in FIG. 9. In this embodiment, the wrist positioning method and the optimal pulse signal selecting method is the same as that in the first embodiment. Their main difference is that the selected optimal pulse signals are used alternatively by the volume oscillation method for noninvasive measurement of the mean and systolic blood pressure and by the volume compensation method for noninvasive measurement of the continuous blood pressure waveform.

The device of this embodiment also comprises an on-wrist detecting device and a pressure supplying and measuring system. Most parts of the on-wrist detecting device and the pressure supplying and measuring system are the same as the above two embodiments. The difference lies in: as shown in FIG. 9, in order to make both intermittent and continuous measurements of the blood pressure waveform, the pressure supplying and measuring system (part 29, 30, and 31 for controlling the reading of the ballonet pressure in FIG. 1) of the first embodiment and the feedback control system (part 34, 35, 36, and 37 for controlling the change of ballonet pressure in FIG. 7) of the second embodiment are alternatively working through an "intermittent measurement-continuous measurement" switching device (39). Since this kind of switching device is very simple, related description is not detailed herein.

For long-term clinic and family monitoring of the blood pressure for patients whose blood pressure changes are either mild or sharp, this embodiment can make it possible to choose the measuring intervals according to the patient's conditions in a range freely from zero to infinity.

Embodiment 4

The fourth embodiment of this invention is to make the intermittent and/or continuous measurement of the blood pressure alternately on radial artery (7) and ulnar artery (9). The wrist positioning method and optimal pulse signal selecting method is the same as that in the above three embodiments. The main difference is that there are two pressure ballonets, i.e. ballonet (3) and ballonet (3'), which are placed separately on radial artery (7) and ulnar artery (9) to measure blood pressure alternately.

In this embodiment, the pulse sensor set inside the arterial pressure ballonet (3) uses the same photoelectric sensor array (4) as in the above embodiments. However, the pulse sensors for ulnar pressure ballonet (3') can only be the shunt-wound photoelectric sensors, and it is preferred to place at least two photoelectric sensors on the circumference of wrist within the pressing scope of ulnar pressure ballonet (3').

In this embodiment, it is necessary to use the result of radial artery blood pressure measurement as a standard to calibrate the result of the ulnar blood pressure measurement on the ulnar artery. That is, calculate the difference (Di) between the mean blood pressure measured from the radial artery (7) and the ballonet pressure of ulnar artery (9) corresponding to the maximum pulse amplitude of ulnar arterial pulse, and at the same time calculate the ratio (Pi) of the ulnar arterial pulse amplitude to the maximum amplitude of the ulnar arterial pulse when the ballonet pressure of ulnar artery (9) is equal to the systolic blood pressure measured from the radial artery (7); each time thereafter, the new mean blood pressure of ulnar artery (9) can be obtained by subtracting Di from the ballonet pressure of ulnar artery corresponding to the maximum amplitude of measured ulnar arterial pulse, while the new systolic blood pressure of ulnar artery can also be obtained by seeking the ballonet pressure corresponding to the point where the ratio of ulnar arterial pulse amplitude to its maximum amplitude is Pi, provided that the ballonet be lower than the new mean blood pressure.

When using the result of radial artery (7) blood pressure measurement as a standard to calibrate the result of the ulnar artery (9) blood pressure measurement, the two pressure ballonets (3 & 3') can be connected by tubing, and then use volume oscillation method to measure radial artery blood pressure and ulnar artery blood pressure at the same time.

Or, when using the result of radial artery (7) blood pressure measurement as a standard to calibrate the result of the ulnar artery (9) blood pressure measurement, blood pressure measurement on radial artery (7) and ulnar artery (9) can be carried out in succession.

During the long-term continuous measurement of blood pressure through the method of this embodiment, Di and Pi values should be automatically re-calculated on the basis of the calibrating method mentioned above.

To implement the method of this embodiment, the device used in the embodiment also comprises a on-wrist detecting device (0) which basically is the same as in the first embodiment. However, as shown in FIG. 10, another pressure ballonet (3') to press the ulnar artery is placed opposite to the existing radial artery pressure ballonet (3) on the ballonet holding strap (5), and also a pulse sensor for detecting the ulnar artery pulse is set inside the ballonet (3'). Also, it can use either of the two independent pressure supplying and measuring systems used in the above three embodiments, and use the switching device to alternate between the intermittent or continuous measurement of blood pressure on either radial or ulnar artery.

In this embodiment, the radial artery pressure ballonet and the radial arterial pulse sensor should have the same structure as that used in the first embodiment, so as to make accurate measurement on the blood pressure of the radial artery like the first embodiment. Ulnar artery pressure ballonet (3') can be the same structure as in the first embodiment, but the ulnar arterial pulse sensor does not need to use a photoelectric sensor array as complicated as used in the radial arterial pulse sensor. The reason is that the ulnar artery (9) is located deeper, and there exist tendons (11) between the skin and the ulnar artery, it is not easy to receive the full pressure of the ballonet (as shown in FIG. 3). As a result, it is hard to make accurate measurement on the ulnar artery blood pressure at any point beyond the outside wrist. Generally, if the pressure of the ballonet falls within a regular range, the maximum point, but not the disappearing point, of the pulse amplitude can be detected at the ulnar artery, and the ballonet pressure corresponding to the maximum point is always higher than mean blood pressure of the artery. However, in order to search the ulnar artery conveniently, it is preferred to place at least two shunt-wound photoelectric sensors along the circumference of the wrist over the ulnar artery. Obviously, under this condition, only one channel of amplifier and filter is required for the ulnar arterial pulse signals, and meanwhile the optimal pulse signal selecting circuit can be omitted.

As the blood pressure on radial artery is basically the same as on ulnar artery for the same examinee, and the gap between the internal pressure of ulnar ballonet (3') and the real pressure put on ulnar artery (9) is basically consistent if the examinee does not rotate its wrist greatly, it is necessary to use the result of radial artery blood pressure measurement as a standard to calibrate the result of the ulnar blood pressure measurement on the ulnar artery for each measurement in this embodiment. When calibrating, connect the two pressure ballonets (3 & 3') by tubing and then use volume oscillation method to measure radial artery blood pressure and ulnar artery blood pressure at the same time. Calculate the difference (Di) between the mean blood pressure measured from the radial artery and the ballonet pressure of ulnar artery corresponding to the maximum pulse amplitude of ulnar arterial pulse, and at the same time calculate the ratio (Pi) of the ulnar arterial pulse amplitude to the maximum amplitude of the ulnar arterial pulse when the ballonet pressure of ulnar artery is equal to the systolic blood pressure measured from the radial artery; each time thereafter, the new mean blood pressure of ulnar artery can be obtained by subtracting Di from the ballonet pressure of ulnar artery corresponding to the maximum amplitude of measured ulnar arterial pulse, while the new systolic blood pressure of ulnar artery can also be obtained by seeking the ballonet pressure corresponding to the point where the ratio of ulnar arterial pulse amplitude to its maximum amplitude is Pi, provided that the ballonet be lower than the new mean blood pressure. It is possible that the Di and Pi do change due to the excessive movement of examinee's wrist, so they must be re-calculated automatically in the same way as the beginning during long-term blood pressure measurement.

To simplify the circuit structure in this embodiment, most parts of the pressure supplying and measuring system, except for pulse signal amplifier, wave filter, optimal pulse signal selector and pulse amplitude detector, can be shared in blood pressure measurement for both radial and ulnar artery. Certainly, one pressure supplying and measuring systems can be completely shared in both blood pressure measurement of radial artery (7) and blood pressure measurement of ulnar artery (9); when measuring the blood pressure for either radial artery or ulnar artery, a switching device is used to alternatively connect the above pressure supplying and measuring systems to the pressure ballonet tubing of the corresponding artery and the signal output. However, this kind of simplification makes the simultaneous retrieval of blood pressure values on both arteries impossible in a single measurement. Therefore, when using the result of radial artery blood pressure measurement as a standard to calibrate the result of the ulnar artery blood pressure measured on the ulnar artery, it is required to make blood pressure measurement on radial artery (7) and ulnar artery (9) in an alternate order. The method of calibration is similar, except that the standard blood pressure value of radial artery is not the one measured when the blood pressure value of ulnar artery is detected, but the one that's sequential.

Since the alternate use of two arteries does not incur pain and numbness as long-term continuous pressure detection on one artery does, this embodiment can greatly prolong the time period for repeated and continuous blood pressure measurement.

Embodiment 5

The method applied in this embodiment is the same as that in above-identified embodiments

The device of this embodiment combines the on-wrist detecting device with pressure sensor, voltage/air pressure sensor, or even all parts of the pressure supplying and measuring system into a whole. There are fewer needs for wiring and tubing so as to be convenient for clinical application. Furthermore, for the continuous measurement of blood pressure based on volume compensation method, this will greatly accelerate the feedback control and improve the precision of the blood pressure waveform measurement.

Embodiment 6

The sixth embodiment of this invention is to combine any of the noninvasive on-wrist blood pressure measurement devices identified in the above five embodiments with any other detecting devices for physiological parameters (e.g. EG, respiration and body temperature) into a whole, forming a multi-function body monitor.

Embodiment 7

The seventh embodiment of this invention is to connect any of the noninvasive on-wrist blood pressure measurement devices identified in the above six embodiments with data recording apparatus (e.g. tape recorder, IC memory) or to combine them into a mini-type article, forming a portable monitor for outdoor blood pressure measurement.

Embodiment 8

The eighth embodiment of this invention is to connect any of the noninvasive on-wrist blood pressure measurement devices identified in the above seven embodiments with wire or wireless communicating apparatus (e.g. radio transmitter, wire or wireless telephone) and form a remote monitoring network for delivering measurement results to medical institutions and retrieving medical advice from medical institutions.

Embodiment 9

The wrist positioning method, the optimal pulse signal selecting method and the measuring method in this embodiment is the same as that in the first embodiment.

However, the device in the ninth embodiment is a kind of simplification and improvement on the basis of the first embodiment. In this embodiment, wrist-holding bracket (6) is omitted. For realization of the correct positioning, examinee should follow the instructions for use of this device, keep the wrist (18) and the lower part of the palm (17) immobile, and keep the angle between the lower part of the palm and the wrist and the turning angle of the wrist relative to the forearm to the most applicable degree for measuring the blood pressure of the radial artery, and then wrap and secure the ballonet holding strap according to the display of optimal pulse sensor position. The mean blood pressure, systolic blood pressure and diastolic blood pressure of radial artery is measured then.

Simple on-wrist blood-pressure meter for daily blood pressure measurement, clinical medical examination or for validating the effect of hypertension treatment can be made according to this embodiment.

The above embodiments are only for illustrating this invention, not for limiting this invention. This invention can also have many other embodiments and improvement plans. For example, in the above four embodiments, we used volume oscillation method for intermittent blood pressure measurement and volume compensation method for continuous blood pressure measurement. In both methods, whether the examinee's arterial pulse oscillation amplitude reaches the maximum is used as the criterion to judge whether or not the examinee's artery blood pressure is at its unloading state, while pressure control is used to control the external pressure on the artery being measured, and photoelectric sensor is used to detect the arterial pulse. In fact, other criteria, such as the shape of the pulse waveform or the change in the level of the base line, the change in the oscillation amplitude of the small vibration wave added artificially to the pulse wave, and the change in the speed of blood flow in the artery being measured, can be used to judge the unloading state of the examinee's artery. In addition, hydraulic pressure control can also be used to control the external pressure on the examinee's artery, and other types of arterial pulse sensor are applicable in this invention.

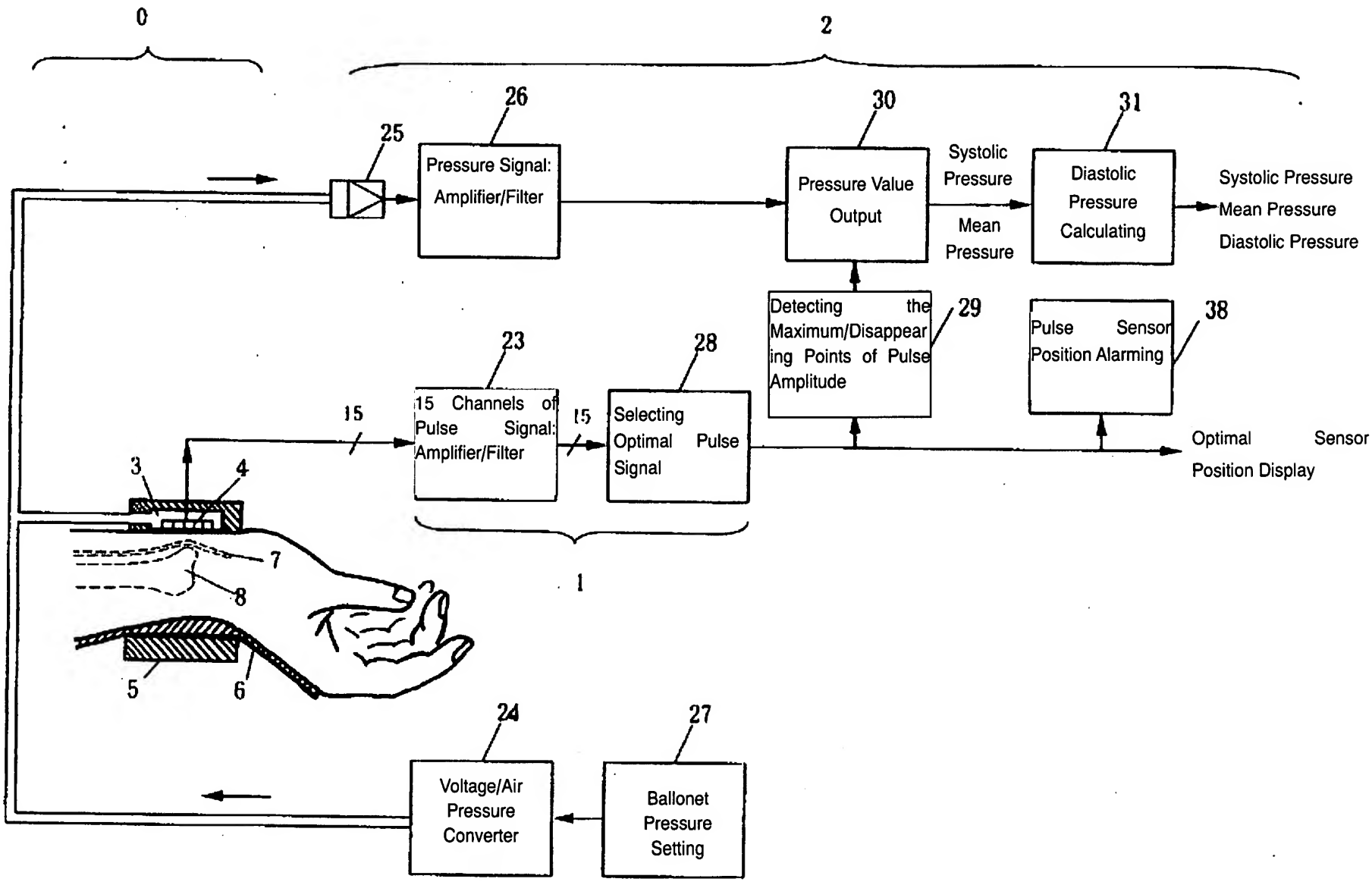
0
2
26
25
Pressure Signal: Amplifier/Filter
30
Pressure Value Output
Systolic Pressure
Mean Pressure
31
Diastolic Pressure Calculating
Systolic Pressure
Mean Pressure
Diastolic Pressure
Detecting the Maximum/Disappearing Points of Pulse Amplitude
29
Pulse Sensor Position Alarming
38
23
28
15
15 Channels of Pulse Signal: Amplifier/Filter
15
Selecting Optimal Pulse Signal
Optimal Sensor Position Display
3
4
7
8
5
6
1
24
27
Voltage/Air Pressure Converter
Ballonet Pressure Setting

FIG 1

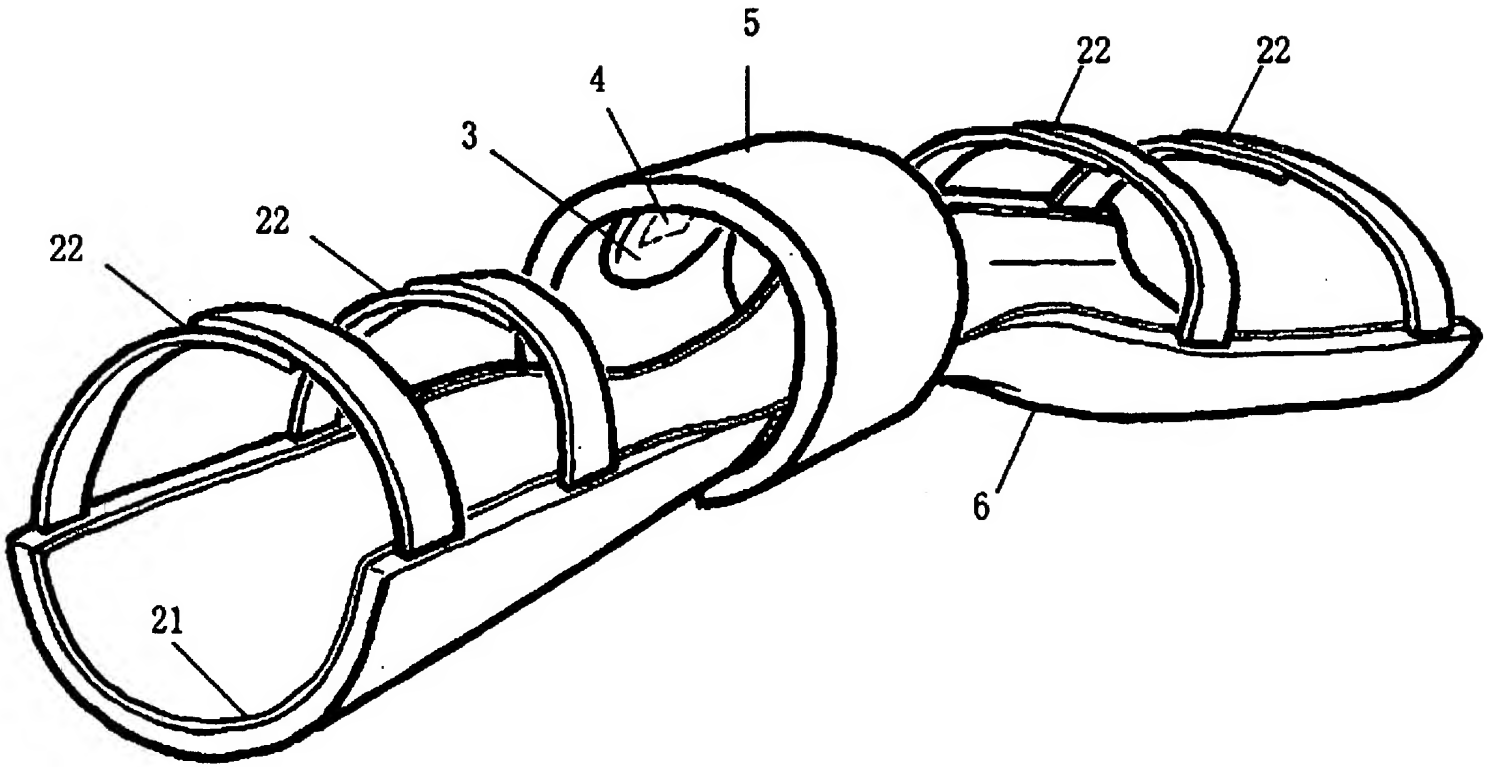

FIG 2

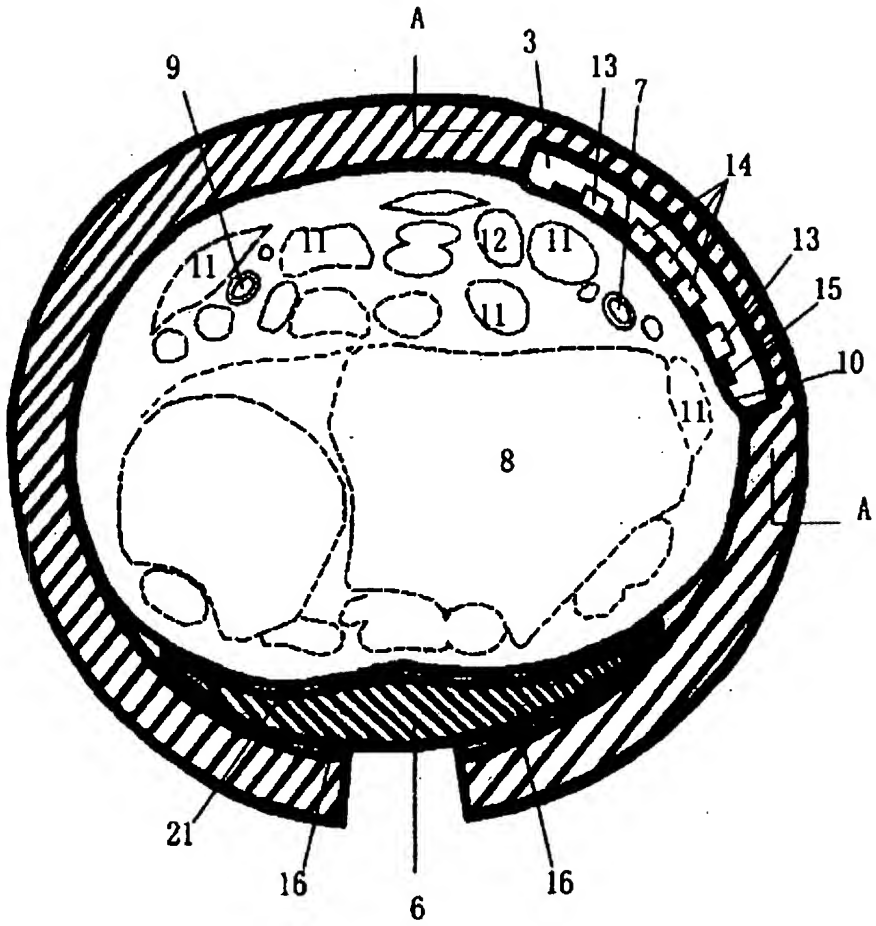

FIG 3

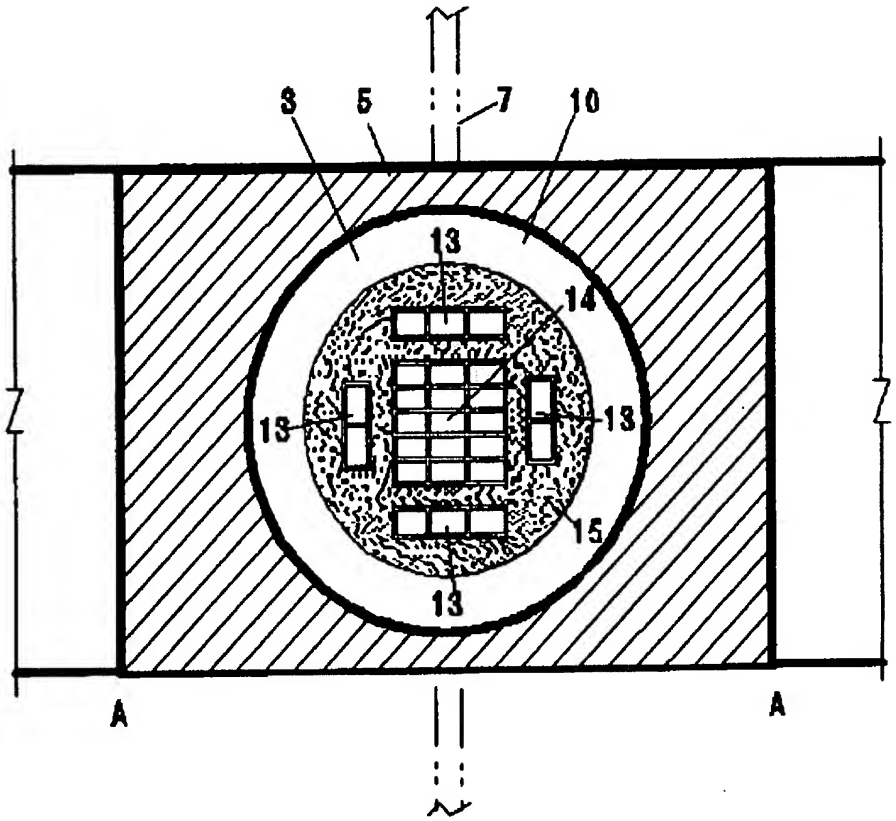

FIG 4

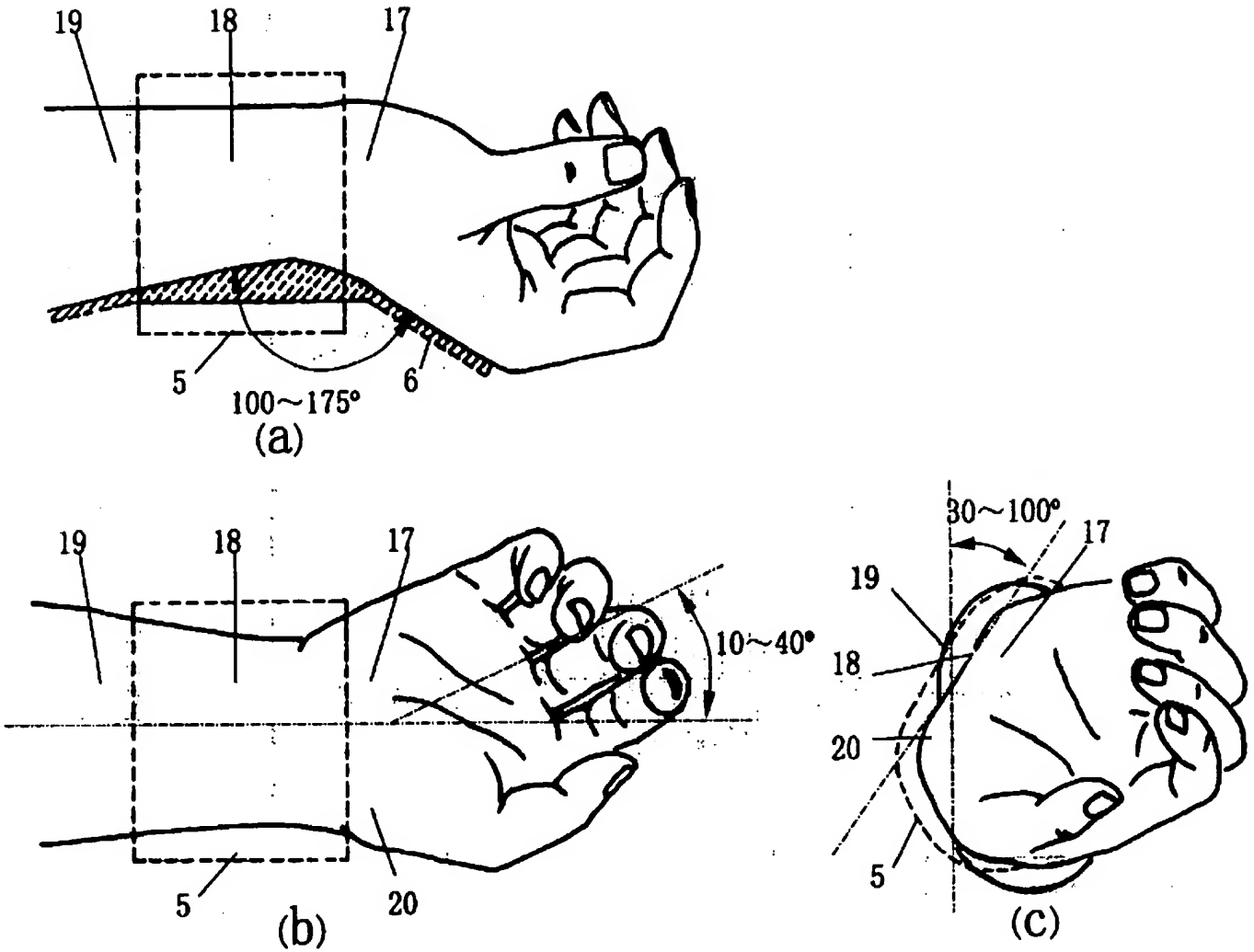

FIG 5

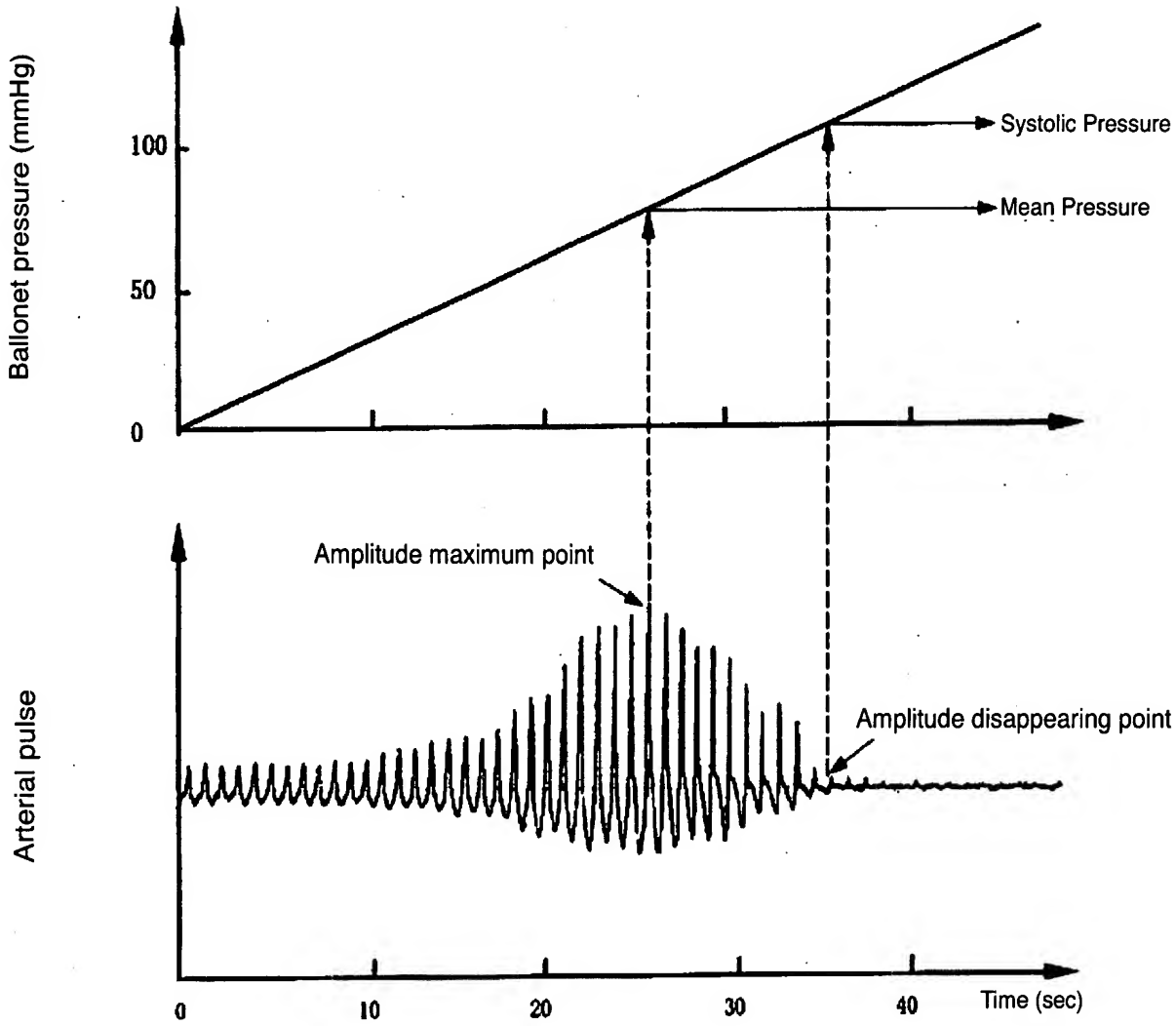
Ballonet pressure (mmHg)
100
50
0
Systolic Pressure
Mean Pressure
Amplitude maximum point
Amplitude disappearing point
Arterial pulse
0
10
20
30
40
Time (sec)

FIG 6

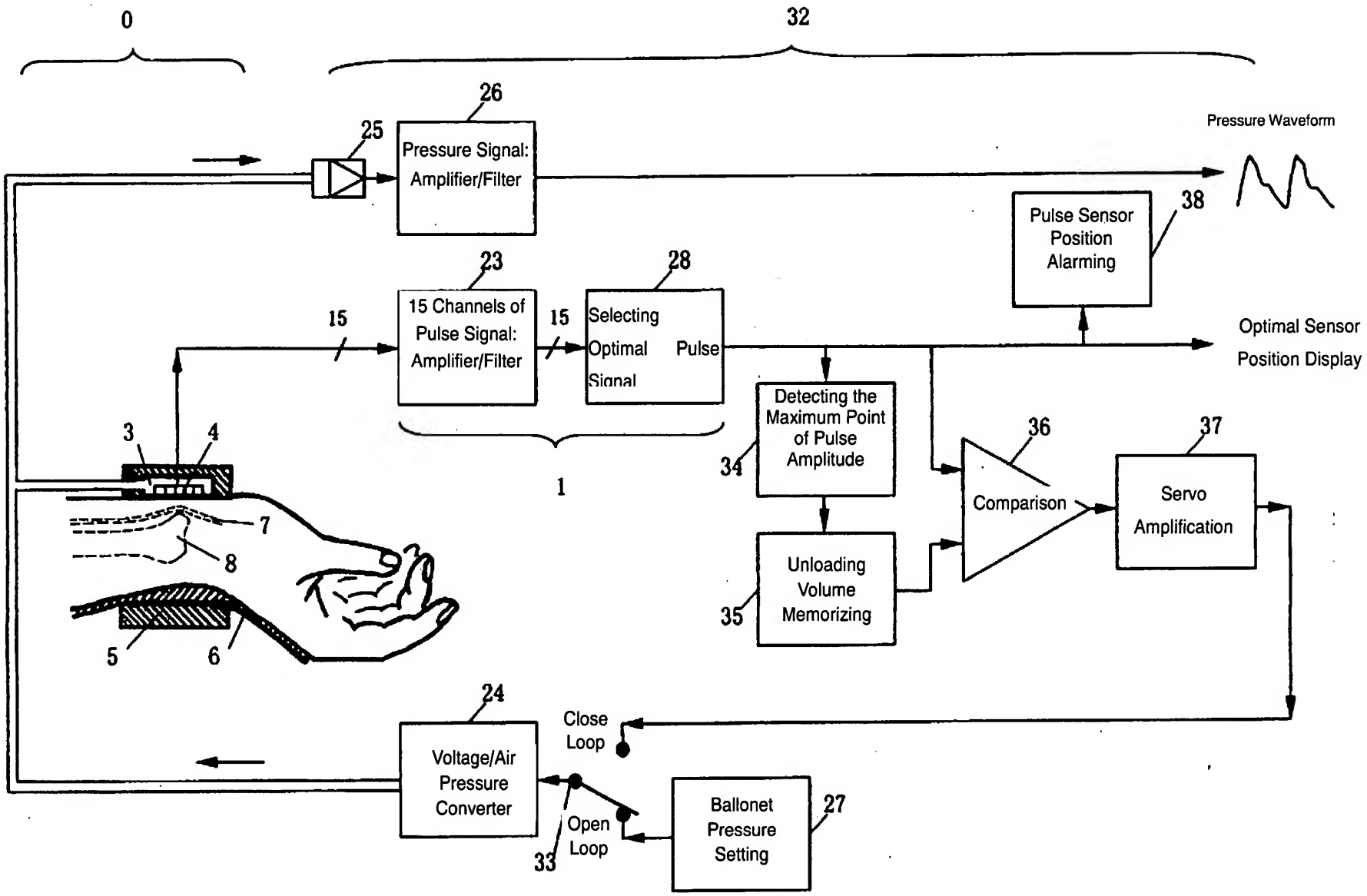
0
32
26
25
Pressure Signal: Amplifier/Filter
Pressure Waveform
Pulse Sensor Position Alarming
38
23
28
15
15 Channels of Pulse Signal: Amplifier/Filter
15
Selecting Optimal Pulse Signal
Optimal Sensor Position Display
Detecting the Maximum Point of Pulse Amplitude
34
36
37
Comparison
Servo Amplification
3
4
7
8
5
6
1
Unloading Volume Memorizing
35
24
Close Loop
Voltage/Air Pressure Converter
Open Loop
33
Ballonet Pressure Setting
27

FIG 7

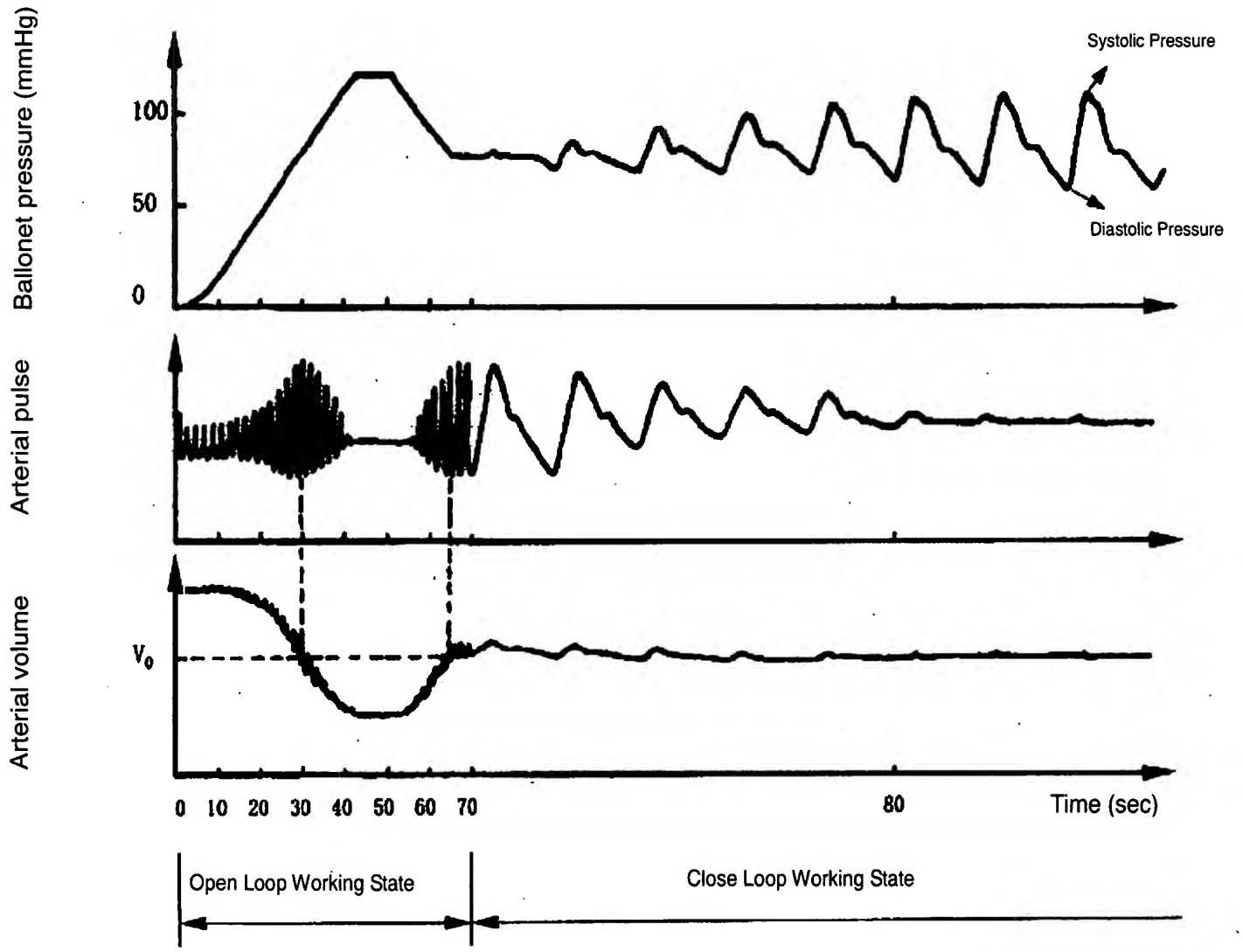
Ballonet pressure (mmHg)
100
50
0
Systolic Pressure
Diastolic Pressure
Arterial pulse
Arterial volume
V_0
0 10 20 30 40 50 60 70
80
Time (sec)
Open Loop Working State
Close Loop Working State

FIG 8

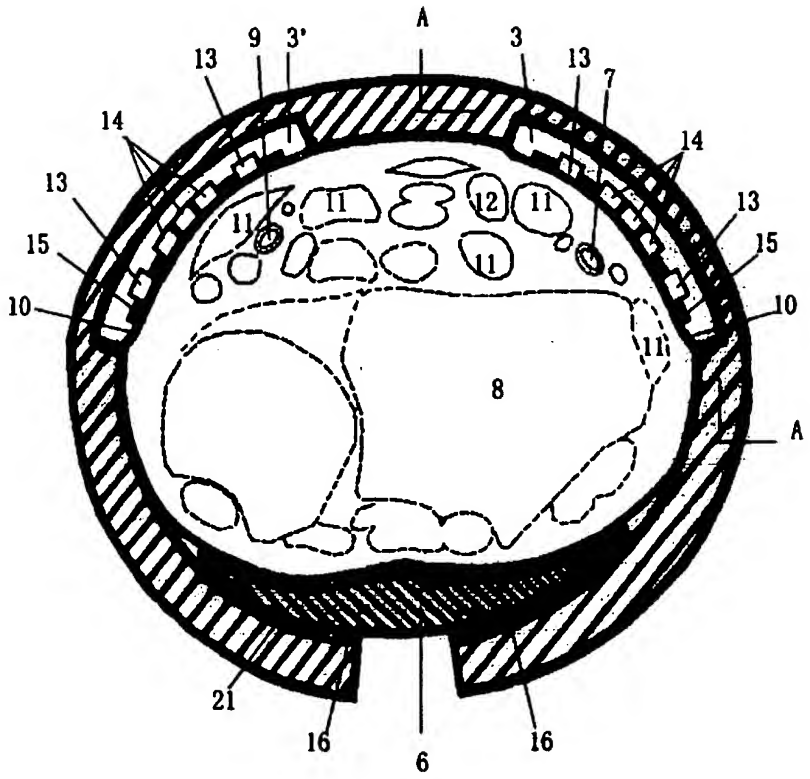

FIG 9

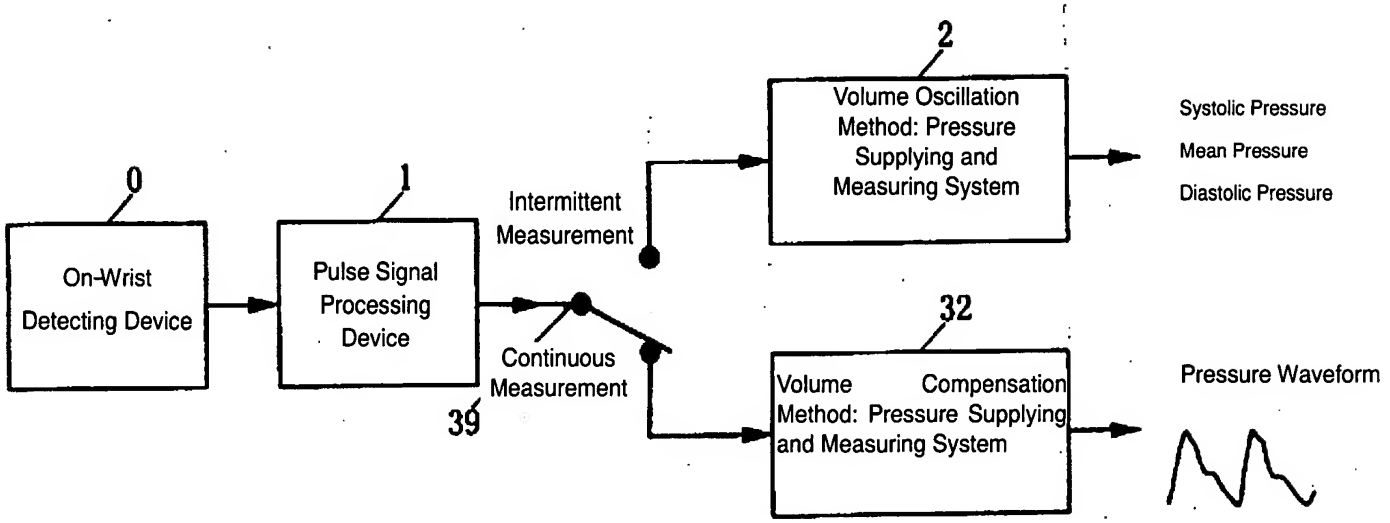
0
On-Wrist
Detecting Device
1
Pulse Signal
Processing
Device
Intermittent
Measurement
Continuous
Measurement
39
2
Volume Oscillation
Method: Pressure
Supplying and
Measuring System
Systolic Pressure
Mean Pressure
Diastolic Pressure
32
Volume Compensation
Method: Pressure Supplying
and Measuring System
Pressure Waveform

FIG 10